UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE PLAVIX® MARKETING, SALES PRACTICE AND PRODUCTS LIABILITY LITIGATION (NO. II)	**MDL DOCKET NO. 2418**
UNITED STATES OF AMERICA, ET AL. V. BRISTOL-MYERS SQUIBB COMPANY, ET AL.	**CASE NO. 3:13-CV-01039-FLW-LHG**

FOURTH AMENDED COMPLAINT

Plaintiff-Relator Elisa Dickson ("Relator" or "Dickson"), through her undersigned attorneys, on behalf of the United States of America ("United States"), and the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Illinois, the State of Indiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Virginia, and the District of Columbia (collectively,

the "Participating States"[1]), for her Fourth Amended Complaint against Defendants Bristol Myers Squibb Company; Sanofi-Aventis U.S., L.L.C.; Sanofi-Aventis U.S., Inc.; and Sanofi-Synthelabo, Inc., alleges as follows:

I.
INTRODUCTION

A. Background Regarding BMS/Sanofi's Marketing of Plavix

1. Plavix® (clopidogrel bisulfate) ("Plavix") is a prescription blood thinner manufactured by Bristol-Myers Squibb Company ("BMS") and co-marketed in the United States by the Sanofi-Aventis Defendants ("Sanofi") (collectively, "BMS/Sanofi"). Plavix is indicated for treatment of Acute Coronary Syndrome and use following a recent myocardial infarction or stroke or established peripheral artery disease.[2] Before it lost its patent protection, Plavix was BMS's number one selling product.[3] For the quarter ending March 31, 2010, BMS reported gross revenue of $4.81 billion with Plavix sales accounting for over 30%

[1] Although the States of Hawaii, Louisiana, and Mississippi have state-law causes of action for the harm done by Defendants as described in this Fourth Amended Complaint, these states are pursuing their claims in state court and have elected not to participate in this federal court action.

[2] *See* Plavix Package Insert at 1-2 and 5-6, attached hereto as Exhibit B ("Ex. B (Plavix Insert)").

[3] *See* Val Brickates Kennedy, *Bristol-Myers Profit Jumps as Plavix Sales Surge*, MARKETWATCH, April 29, 2010, attached hereto as Exhibit C.

of that total ($1.67 billion).[4] Until 2012, BMS enjoyed patent protection over clopidogrel bisulfate, and there were no generic versions available on the market.[5]

2. Defendants Sanofi and BMS have a marketing partnership under which they jointly market the prescription drug Plavix.[6] All efforts to promote Plavix are jointly administered by BMS/Sanofi. All Plavix advertisements, brochures, and promotional materials feature both the BMS and Sanofi names.[7]

3. Plavix costs approximately $4.00 per pill, whereas aspirin costs approximately $0.04 per pill.[8] This action arises out of BMS/Sanofi's practice of promoting Plavix as a superior drug to aspirin for certain indicated usages and charging approximately 100 times more for Plavix than could be charged for aspirin, when in fact Plavix is no more effective than aspirin for certain indicated usages. BMS/Sanofi targeted such efforts at physicians and prescribers whose patients relied upon public assistance programs such as Medicaid, Medicare, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"),

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[4] *Id.*

[5] *See* FDA News Release, May 17, 2012, *FDA Approves Generic Versions of Blood Thinner Plavix*, available at http://goo.gl/3oAWQ (last visited Oct. 15, 2015).

[6] Linda Johnson, *Bristol-Myers, Sanofi Revamp Plavix Sales Alliance*, Oct. 3, 2012, *available at* http://bigstory.ap.org/article/bristol-myers-sanofi-revamp-plavix-sales-alliance (last visited Oct. 15,2015) (discussing BMS/Sanofi's "longtime partnership" selling Plavix).

[7] *See id.*

[8] Affidavit of Relator-Plaintiff Elisa Dickson ¶ 8, attached hereto as Exhibit A ("Ex. A (Affidavit)").

and other government funded public assistance programs ("Government Payors.").[9] BMS/Sanofi thereby caused physicians to submit many prescriptions for Plavix in the mistaken belief that it was a cost-effective treatment when, in fact, those prescriptions resulted in grossly inflated costs for Government Payors (and, therefore, taxpayers) with no additional benefit to the covered patient when compared to aspirin. In addition, BMS/Sanofi fraudulently induced state review boards to place Plavix on their respective state's formulary for indications for which Plavix was neither medically necessary nor cost effective and to pay false claims for Plavix once the drug was placed on the state's formulary.

B. FDA Regulatory Action Concerning the Promotion of Plavix

4. On November 23, 1998, FDA's Division of Drug Marketing and Communications ("DDMAC") sent a letter (the "November 1998 Letter")[10] to Defendant Sanofi concerning letters Defendant sent to physicians regarding the use of 300 mg of Plavix as a "loading dose" immediately prior to coronary stent placement.

5. At the time of the letter, the recommended dose of Plavix was 75 mg per day. The use of 300 mg of Plavix as a "loading dose" for coronary stent

[9] Although BMS/Sanofi's scheme to cause false claims for Plavix was directed at Government Payors for a variety of public assistance programs, this lawsuit is bringing claims on behalf of Government Payors under Medicaid.

[10] *See* Letter from DDMAC dated Nov. 23, 1998, attached hereto as Exhibit O ("Ex. O (November 1998 Letter)").

placement patients was neither proven to be safe or efficacious nor supported by substantial clinical evidence.

6. The November 1998 Letter concluded in relevant part:

> DDMAC is very concerned with the dissemination of the Letter because it states or suggests that Plavix is safe and effective in patients undergoing stent procedures, at an off-label dose, and in patients who will be concomitantly receiving other antiplatelet and/or anticoagulant agents. Further, no risk information was provided in the Letter to alert the reader to the adverse events associated with Plavix therapy. Because Plavix is associated with hemorrhagic adverse events at the recommended 75 mg/day dose, promotion of Plavix in patients receiving coronary artery interventions, at four times the recommended dose, in combination with other agents known to increase the risk of bleeding, raises significant patient safety concerns.[11]

7. Consequently, the FDA identified that Plavix "is associated with hemorrhagic adverse events at the recommended 75 mg/day dose" and identified that Defendant Sanofi's marketing efforts "rais(ed) significant patient safety concerns."[12]

8. On May 9, 2001, DDMAC sent another letter to Defendant Sanofi objecting to its promotional efforts for Plavix and stated that the Defendant was "in violation of the Federal Food, Drug and Cosmetic Act and its implementing regulations."[13]

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[11] *Id.* at 2.

[12] *Id.*

[13] Letter from DDMAC dated May 9, 2001, attached hereto as Exhibit P ("Ex. P (May 9, 2001 Letter)").

9. DDMAC identified a Plavix sales aid, 69-201499, and stated that the sales aid contained "promotional claims that were false and misleading."[14]

10. Specifically, DDMAC found that the sales aid overstated the efficacy of Plavix, made unsubstantiated superiority claims, constituted a misleading efficacy presentation and lacked fair balance.[15]

11. Of particular importance is DDMAC's evaluation of Defendants' unsubstantiated superiority claims concerning Plavix vis-à-vis aspirin, which reads in relevant part:

> On page 4 of the visual aid you present the claim, "Significant overall risk reduction vs. aspirin 325 mg in CAPRIE, a 3 year study of 19,185 patients." This claim is misleading because it suggests that Plavix is superior to aspirin when such has not been demonstrated by substantial evidence. As previously stated in our December 18, 1998, untitled letter, the CAPRIE trial does not provide substantial evidence to support the implication that Plavix has superior efficacy over aspirin. Therefore, claims suggesting that Plavix is significantly better than aspirin are misleading because they are not based on substantial evidence.[16]

12. Despite DDMAC's conclusion that "the CAPRIE trial does not provide substantial evidence to support the implication that Plavix has superiority over aspirin,"[17] over ten years later Defendants nevertheless continue to promote

[14] *Id.*
[15] *Id.*
[16] *Id.* at 2.
[17] *Id.*

that Plavix is superior to aspirin despite the fact that no study has generated evidence that supports that claim.

13. On March 26, 2009, DDMAC sent another letter to Defendant Sanofi after determining that Plavix internet advertisements misbranded Plavix and were "in violation of the Federal Food, Drug and Cosmetic Act and its implementing regulations."[18]

14. DDMAC concluded that Sanofi failed to provide any risk information and stated in relevant part:

> These sponsored links make representations and/or suggestions about the efficacy of PLAVIX, but fail to communicate any risk information. For promotional materials to be truthful and non-misleading, they must contain risk information in each part as necessary to qualify any claims made about the drug.
>
> By omitting the most serious and frequently occurring risks associated with PLAVIX, the sponsored links misleadingly suggest that PLAVIX is safer than has been demonstrated.[19]

C. Relator Dickson's Knowledge of BMS/Sanofi's Scheme to Defraud the Government

15. BMS and Sanofi have knowingly participated in a comprehensive scheme to defraud federal and state governments by illegally and deceptively promoting Plavix as superior to aspirin to increase Plavix sales at taxpayer expense. Dickson has worked in the pharmaceutical industry for approximately

[18] Letter from DDMAC dated March 26, 2009, attached hereto as Exhibit Q ("Ex. Q (March 26, 2009 Letter)").

[19] *Id.* at 2.

twelve years and was formerly a sales representative specializing in selling Plavix.[20] She has direct and independent knowledge of the information on which the allegations are based.[21] Dickson took a position as a sales representative at Sanofi in 2003.[22] Her duties included selling Plavix, in addition to other drugs.[23] From 2008 to 2010, Dickson's primary sales efforts were concentrated on selling Plavix to primary care physicians (family practice, general practice, and internal medicine) to prevent ischemic strokes in patients who had experienced a recent stroke and for the reduction of atherothrombotic events in patients with established Peripheral Arterial Disease, recent stroke, recent myocardial infarction, or acute coronary syndrome.[24]

16. Dickson's initial training for selling Plavix consisted of several weeks of both home study and classroom training in St. Louis, Missouri during September 2003.[25] Her training did not focus solely on Plavix and also included other drugs.[26] In 2008, Dickson attended a two day refresher course on Plavix in Dallas, Texas.[27] This training was limited; it did not provide thorough background

[20] *See* Ex. A (Affidavit).
[21] *See id.*
[22] *Id.* ¶ 4.
[23] *Id.*
[24] *Id.* ¶ 5.
[25] *Id.* ¶ 6.
[26] *Id.*
[27] *Id.*

and knowledge on the Plavix studies that had been published since 2006 such as the Aggrenox study PRoFESS.[28]

17. Prior to losing its patent protection, Plavix was a major producer of revenue and market share for BMS/Sanofi. For example, according to marketing data Dickson received from Sanofi, Plavix was prescribed for approximately 31% of patients who had experienced a recent stroke.[29] Prescriptions of Plavix for recent stroke victims generated approximately $666 million in annual sales for Sanofi (roughly 10% of an estimated $7 billion in total annual Plavix sales).[30]

i. BMS/Sanofi's False Statements Regarding Plavix

18. As a member of the sales force, Dickson was instructed by Sanofi and, based on these instructions, regularly promoted Plavix as having certain characteristics that BMS/Sanofi knew were false.[31]

19. For instance, despite the non-significant efficacy data in certain trials for stroke patients, Sanofi instructed Dickson to promote Plavix as being superior to aspirin in stroke patients.[32] Also, company sales pamphlets citing these trials claimed that there was "proven efficacy" of Plavix over aspirin in ischemic stroke

[28] *Id.*
[29] *Id.* ¶ 9.
[30] *Id.*
[31] *See* Ex. A (Affidavit).
[32] *Id.* ¶ 16-18.

patients.[33] In fact, Sanofi required that Dickson promote Plavix as comparably safe to aspirin based on one study even though that study compared Plavix to a more toxic dose of aspirin that is not regularly prescribed today.[34] Dickson was also instructed to encourage physicians to switch patients from aspirin to Plavix if they suffered a stroke while taking aspirin.[35]

20. Dickson was instructed to present the data from yet another study in a manner designed to confuse physicians and make them believe that Aggrenox (aspirin + dipyridamole) was inferior to Plavix.[36] Rather than state that the study showed no difference between the two drugs, Dickson was instructed to emphasize that "Aggrenox failed to achieve the primary endpoint of non-inferiority for recurrent stroke in stroke patients" and further that "major hemorrhagic events and intracranial bleeds were observed more frequently in the Aggrenox group."[37] She also was instructed to state that "it should not be concluded from the study that Aggrenox has similar efficacy and safety to Plavix in stroke patients."[38] The

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[33] *Id.* ¶ 16; *see The Efficacy and Safety of PLAVIX in Ischemic Stroke Patients – A Case-Based Approach*, attached hereto as Exhibit D, at 4 ("Ex. D (Efficacy and Safety of PLAVIX)").

[34] Ex. A (Affidavit) ¶ 22.

[35] *Id.* ¶ 19.

[36] *Id.* ¶ 31.

[37] *Id.*; *Summary of PRoFESS (Prevention Regimen for Effectively Avoiding Second Strokes)*, attached hereto as Exhibit E ("Ex. E (PRoFESS Summary)"), at 5.

[38] Ex. A (Affidavit) ¶ 31; Ex. E (PRoFESS Summary) at 5.

purpose of talking to physicians about this particular trial was to increase Plavix's market share.[39]

ii. BMS/Sanofi's Comprehensive Scheme to Defraud the Government

21. Dickson's training and sales experience is powerful evidence of BMS/Sanofi's comprehensive scheme to defraud federal and state governments by illegally and deceptively promoting Plavix to increase Plavix sales. In particular, BMS/Sanofi manipulated clinical trial data to support fraudulent claims regarding Plavix's efficacy relative to cheaper alternatives, such as aspirin. BMS/Sanofi mischaracterized clinical studies that contradicted the sales campaign. While promoting this false narrative regarding Plavix's efficacy compared to cheaper alternatives like aspirin, BMS/Sanofi targeted doctors whose patients rely on Government Payors for health care treatment so as to wrongfully inflate sales and profits at a tremendous cost to American taxpayers. For example, Dickson was instructed by Sanofi to focus sales calls on physicians who wrote significant numbers of prescriptions for patients covered by certain Government Payors.[40] According to Dickson, the purpose of targeting such patients was that there was less resistance by physicians to prescribing expensive drugs due to the fact that the government was paying for the medication rather than the patient.[41]

[39] Ex. A (Affidavit) ¶ 33.
[40] *Id.* ¶ 34.
[41] *Id.* ¶ 35.

22. More than half of state Medicaid programs contain cost-based restrictions that limit coverage under Medicaid to cost-effective treatments. In these states, Medicaid only pays for cost-effective drugs. Where an equally effective but cheaper treatment is available for a particular course of treatment, the more expensive drug is not cost effective and cannot be reimbursed. In these states, cost effectiveness is not just a requirement for participation in Medicaid, it is a condition precedent to reimbursement designed to ensure that a state's Medicaid program is a good steward of taxpayer dollars. For example, the State of Washington was sued recently by Medicaid subscribers who were upset that Washington refused to pay for "breakthrough" Hepatitis C drugs for one reason: "they are expensive."[42]

23. In addition, Plavix is a prescription drug; it cannot be reimbursed without a prescription. Thus, writing a prescription for Plavix is not some ministerial task. It is a determinative condition precedent to reimbursement. Prescribing physicians are the Government Payor's final line of defense to prevent reimbursement of a drug that is not cost effective. Because Plavix is no more effective than aspirin for certain indications and is extraordinarily more expensive than aspirin, BMS/Sanofi's scheme to regularly and systematically present Plavix

[42] *B.E. & A.R. v. Teeter*, Complaint, Case No. 2:16-cv-00227-JCC, in the United States District Court for the Western District of Washington (filed Feb. 2, 2016).

to physicians (particularly, physicians with high volume Government Payor patients) as superior to aspirin for certain patients caused doctors to prescribe an unnecessary, high-cost prescription drug for Medicaid patients when a cheaper, over-the-counter alternative (e.g., aspirin) would have been at least equally effective.

24. BMS/Sanofi's false marketing prevented physicians from making an informed decision regarding whether Plavix was a medically necessary and cost-effective treatment for their patients, thereby causing physicians to write prescriptions for Plavix when aspirin would have been at least equally effective at a fraction of the cost. That is, Defendants' false marketing caused physicians to conclude (wrongfully) that Plavix was medically necessary and cost effective. These unnecessary and costly prescriptions for Plavix caused claims for government payment to be submitted for Plavix when the drug was neither medically necessary nor cost effective. By causing physicians to write prescriptions for Plavix when it was neither medically necessary nor cost effective, BMS/Sanofi caused physicians to falsely certify that Plavix met Medicaid's requirements for payment when it did not. And these prescriptions—which were false certifications that Plavix met program requirements—caused the Government Payors to reimburse the cost of Plavix prescriptions, when such reimbursements were prohibited by the various Medicaid regimes. Accordingly, BMS/Sanofi

caused the submission of numerous false claims for Plavix in states with Medicaid programs that only pay for cost-effective treatments.

25. In addition, each state maintains a formulary or preferred drug list (referred to herein as a "formulary") which exempts certain Medicaid-eligible drugs from a prior authorization requirement. Specifically, federal law authorizes state Medicaid programs to exclude a drug if "the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes of such treatment for such population over other drugs included in the formulary."[43] That is, a state may exclude a drug from its formulary if the drug is not more therapeutically effective for a particular indication than other drugs that treat the same condition. In addition, a state may place reasonable restrictions on prescription drugs covered by Medicaid, including restrictions relating to costs. States, therefore, may also exclude drugs that are not cost effective from the formulary.

26. For drugs that are on the formulary, Medicaid programs are required to reimburse the cost of a drug on a state's formulary when the drug is prescribed by a physician for an indication for which the drug is on the formulary. Thus, if a drug is on a state's formulary, once an "on-label" prescription for that drug is written and the prescription is filled, the cost for that prescribed drug is

[43] 42 U.S.C. § 1396r-8.

automatically reimbursed by Government Payors. No other authorizations are required.

27. Because the states are, in essence, waiving the prior approval requirement for payment by approving a drug for placement on the state formulary, the formulary committee functions as an important gate keeper to prevent drugs that have limited therapeutic benefit or are not cost-effective from receiving automatic reimbursement. And, for formulary drugs, a doctor's prescription is all the more important and powerful. A false implied certification by a doctor that a particular drug is medically necessary and cost effective for a particular patient (i.e., a prescription) is not just material to the Government Payor's payment decision, it is determinative because that prescription results in Government Payor reimbursement despite its falsity.

28. Accordingly, BMS/Sanofi's conduct in maneuvering Plavix onto each state's formulary cannot be overlooked. BMS/Sanofi fraudulently induced state review boards to place Plavix on their respective state's formulary for indications for which Plavix was neither medically necessary nor cost effective and to pay false claims for Plavix once the drug was placed on the state's formulary. Each time the cost of a prescription of Plavix was reimbursed by the federal and/or state government because Plavix was on a state formulary, the reimbursement was based on material fraudulent misrepresentations about the cost effectiveness of Plavix as

compared to aspirin for certain indications. These material misrepresentations caused claims for reimbursement of Plavix to be paid by Government Payors when Plavix was neither medically necessary nor cost effective to treat patients' medical conditions.

II.
PARTIES

29. Relator Dickson is a citizen of the United States. Relator is currently a resident of the State of Arkansas.

30. Defendant Bristol-Myers Squibb Company is incorporated in the state of Delaware with its corporate headquarters in New York, New York. BMS is doing business in the Southern District of Illinois. Defendant has been served with process in this matter.

31. Defendant Sanofi-Aventis U.S., L.L.C. is a Delaware corporation doing business in New Jersey. Sanofi-Aventis U.S., L.L.C. is doing business in the Southern District of Illinois. Defendant has been served with process in this matter.

32. Defendant Sanofi-Aventis U.S., Inc. is a Delaware corporation doing business in New Jersey. Sanofi-Aventis U.S., Inc. is doing business in the Southern District of Illinois. Defendant has been served with process in this matter.

33. Defendant Sanofi-Synthelabo, Inc. is a Delaware corporation doing business in New Jersey. Sanofi-Synthelabo, Inc. is doing business in the Southern District of Illinois. Defendant has been served with process in this matter.

34. Collectively, Defendant Sanofi-Aventis U.S., L.L.C., Defendant Sanofi-Aventis U.S., Inc., and Defendant Sanofi-Synthelabo, Inc. are referred to as "Sanofi."

III.
JURISDICTION AND VENUE

35. This Court has jurisdiction over, and is the proper venue for, this action because the United States Judicial Panel for Multidistrict Litigation ordered this action to be transferred to this Court for centralization on February 12, 2013.

36. Jurisdiction and venue are proper in the Southern District of Illinois, where the case was originally filed, and will be transferred after the completion of the discovery portion of the lawsuit, for the following reasons:

a. Any action under Section 3730 of the False Claims Act may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by Section 3729 occurred.[44] Additionally, the district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises

[44] 31 U.S.C. § 3732(a).

from the same transaction or occurrence as an action brought under Section 3730.[45] Therefore, jurisdiction for the Southern District of Illinois exists pursuant to the False Claims Act (31 U.S.C. § 3730(b)(1) and 31 U.S.C. § 3732(a) and (b)) because Dickson's claims seek remedies on behalf of the United States and the Participating States for Defendants' multiple violations of 31 U.S.C. § 3729, some of which occurred in the Southern District of Illinois, and because the Defendants transact other business within the Southern District of Illinois.

b. Venue is proper in the Southern District of Illinois pursuant to 31 U.S.C. § 3730(b)(1) and 31 U.S.C. § 3732(a) because Defendants are qualified to do business in the State of Illinois and conduct business within the State of Illinois and within the Southern District, and at least one of the Defendants transacts business or committed acts proscribed by 31 U.S.C. § 3729 in the Southern District of Illinois.

IV.
STATUTORY BACKGROUND

A. Medicaid

37. Medicaid is a government health insurance program covering children, the aged, blind, and/or disabled and other people who are eligible to receive federally assisted income maintenance payments.

[45] *Id.* § 3732(b).

38. Under the Medicaid Act, the federal government and the states jointly fund the Medicaid program, with the federal government contributing approximately between 50% and 83% of the funding and the states being responsible for the rest.[46]

39. States that elect to participate in Medicaid must establish and administer their own Medicaid programs. Within broad federal guidelines, each state may determine the type, amount, duration and scope of services to provide in its Medicaid program.

40. Under this framework, states must provide certain mandatory benefits, such as inpatient hospital care and laboratory and x-ray services,[47] and they may choose to provide other optional benefits. Prescription drug coverage is an optional service that states are not required to provide through Medicaid.[48] All fifty states, however, have elected to provide coverage for prescription drugs under Medicaid. Prescription drug coverage, however, is not a mandatory service. The states may place reasonable restrictions on prescription drugs that will be covered, including reasonable restrictions relating to costs.[49]

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[46] 42 U.S.C. § 1396(d); *Pennsylvania Med. Soc. v. Snider*, 29 F.3d 886, 888-89 (3rd. Cir. 1994).

[47] 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a).

[48] *See* 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(12).

[49] *See Pharm. Research & Mfrs. Of Am v. Walsh*, 538 U.S. 644, 666 (2003); *Beal v. Doe*, 432 U.S. 438, 444 (1977); *In re Plavix Mktg., Sales Practices & Prods. Liab. Litig.*, 123 F. Supp. 3d 584, 610 (D.N.J. Aug. 20 2015).

41. At least more than half of the states (if not all the states) participating in Medicaid have included in their Medicaid programs a requirement that prescription drugs be cost effective in order to qualify for reimbursement. In these states (the "Cost-Imposed States"), cost effectiveness is a condition of government payment—a condition which, if the government knew was not being followed, would cause it to actually refuse payment. Simply put, a high cost prescription drug does not qualify for Medicaid reimbursement when there is a cheaper, equally effective alternative drug in the market.[50]

B. Federal False Claims Act

42. This is an action to recover damages and civil penalties on behalf of the United States and Relator Dickson arising from false or fraudulent statements, claims, and acts by Defendants made in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733 (the "FCA").

43. For conduct occurring before May 20, 2009, the False Claims Act provides in pertinent part that:

[50] The Cost-Imposed States include at least Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Washington, Wisconsin, and Wyoming. As detailed in this Complaint, these states require cost-effectiveness as a condition of Medicaid prescription drug coverage. In addition, based on information and belief, each of the Medicaid regimes of each of the other states and the District of Columbia also requires that prescription drug treatment be cost effective in order to qualify for coverage.

(a) Any person who

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; [or]

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(7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government

is liable to the Government for a civil penalty of not less than $5,000 and not more than $10,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.[51]

44. For conduct occurring on or after May 20, 2009, the False Claims Act provides that any person who:

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

[51] *See* History to 31 U.S.C. § 3729 (providing text prior to May 20, 2009 amendments).

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(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. § 2461 note; Pub. L. No. 104-410), for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.[52]

45. The False Claims Act allows any persons having knowledge of a false or fraudulent claim against the Government to bring an action in federal district court for themselves and for the United States Government and to share in any recovery as authorized by 31 U.S.C. § 3730.

C. BMS/Sanofi Caused the Submission of False Claims by Misleading Doctors to Prescribe Plavix when Plavix did not Meet the Requirements for Medicaid Coverage

46. As detailed in Dickson's testimony, BMS/Sanofi promoted Plavix as a superior drug to aspirin for certain indicated uses and charged approximately 100 times more for Plavix than could be charged for aspirin when in fact Plavix was no more effective than aspirin for certain indicated uses. Upon information and belief, BMS/Sanofi marketed Plavix to doctors whose patient populations were

[52] 31 U.S.C. § 3729(a).

composed of Government Payor subscribers. BMS/Sanofi's conduct caused physicians to submit many prescriptions for Plavix that resulted in grossly inflated costs for Government Payors with no additional benefit to the covered patient, when compared to aspirin.

47. The Cost-Imposed States would have refused to pay for Plavix for certain Medicaid patients had they had known that Plavix was no more effective than aspirin for certain indications, because Plavix was 100 times more expensive than aspirin. But because of BMS/Sanofi's fraudulent conduct, prescribing physicians were misled into prescribing Plavix for Medicaid subscribers—which prescriptions certified to the Cost-Imposed States that Plavix met the requirements for Medicaid reimbursement—namely that the drug was medically necessary and cost effective for each patient receiving a prescription for Plavix. Where Plavix is on the formulary, these false certifications resulted in the automatic reimbursement of Plavix.

48. Had the prescribing physicians known the truth about Plavix, they would not have prescribed (because to do so would have been patently against Medicaid requirements), and false claims for Plavix would not have been made. The false implied certification that Plavix met the Cost-Imposed States' Medicaid requirements (i.e., the prescription), therefore, was more than just material to the Government Payor's payment decision; it was outcome determinative. Without a

prescription for Plavix—which was caused by BMS/Sanofi's fraudulent and misleading conduct—Government Payors would not have been saddled with needless, and expensive, false claims.

49. Based on these provisions, Dickson, on behalf of the United States Government, seeks through this action to recover damages and civil penalties arising from BMS/Sanofi's false and/or fraudulent conduct in connection with its false statements regarding the medical necessity and cost effectiveness of Plavix. Dickson believes that the United States has suffered significant damages as a result of BMS/Sanofi's false and/or fraudulent conduct.

50. A claim submitted to the government for payment that does not comply with the applicable statutes or regulations, and where compliance is a precondition to payment, is a false claim under the FCA and the State FCAs (defined below).

51. This is an action to recover damages and civil penalties on behalf of the United States, the Cost-Imposed Participating States (defined below),[53] and Relator Dickson for Medicaid false claims arising from certain Plavix prescriptions

[53] The following are Participating States that are also Cost-Imposed States: Colorado, Connecticut, Delaware, Florida, Georgia, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, North Carolina, Oklahoma, Rhode Island, Tennessee, and Wisconsin (collectively, "Cost-Imposed Participating States").

made from March 30, 2005 (except as provided in the footnote, below),[54] to the present in the Cost-Imposed States that did not satisfy each state's medical necessity and cost-effectiveness requirements for Medicaid reimbursement.

a. The United States and Relator Dickson seek to recover damages and civil penalties for the portion of Medicaid payments made by the federal government for certain Plavix prescriptions in all Cost-Imposed States (as described below).

b. Each of the Cost-Imposed Participating States is a Cost-Imposed State that also has a State FCA. Therefore, each of the Cost-Imposed Participating States and Relator Dickson seek to recover damages and civil

[54] The FCA and most of the State FCAs provide for a six-year limitations period. Accordingly, Relator is not seeking recovery under the FCA or the State FCAs for false claims arising prior to March 30, 2005 except in the following states: New Mexico, New York, Texas, and Wisconsin. These states have longer or shorter limitations periods. *See* New York False Claims Act, N.Y. STATE FIN. LAW § 192(1) (10 years); Wisconsin Limitation of Actions for False Claims, Wis. Stat. Ann. § 893.981 (10 years); New Mexico Medicaid False Claims Act, N.M. STAT ANN. § 37-1-4 (4 years); *United States. ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 818 (E.D. Tex. 2008) (holding Texas FCA claims are subject to a four-year statute of limitations under TEX. CIV. PRAC. & REM. CODE § 16.051). Accordingly, for claims arising under New York's State FCA, Relator is seeking recovery for false claims arising on or after May 30, 2001. For claims arising under Wisconsin's State FCA, Relator is seeking recovery for false claims arising on or after May 30, 2001. For claims arising under New Mexico's State FCA, Relator is seeking recovery for false claims arising on or after May 30, 2007. For claims arising under Texas's State FCA, Relator is seeking recovery for false claims arising on or after May 30, 2007.

penalties under the applicable State FCA for the portion of Medicaid reimbursements made for certain Plavix prescriptions by that particular State.

52. As authorized by the federal government, Medicaid agencies in the Cost-Imposed States have imposed reasonable coverage restrictions based on cost. In each of the Cost-Imposed States, a treatment must be cost effective to qualify for coverage under Medicaid. Cost-Imposed States do not pay for drugs that are not cost effective. A prescription drug is not cost effective and does not qualify for coverage when there is at least an equally effective, cheaper alternative available on the market.

53. Upon information and belief, at all relevant times, each of the Cost-Imposed States' Medicaid regimes included provisions requiring that prescription drug treatment be cost effective in order to qualify for coverage. For example:

54. In Alabama, state law provides that "Alabama should strive to provide appropriate, safe, effective, and cost-efficient pharmaceutical care to those who depend on health benefits through state funded programs."[55] Further, "[t]he Alabama Medicaid Agency should endeavor to manage the Medicaid Pharmacy Program utilizing clinical management tools in a manner to foster optimal health outcomes at reasonable costs."[56] Accordingly, in Alabama, "Medicare and Medicaid authorize payment only when the items or services are medically

[55] ALA. CODE 1975 § 22-6-120(1).
[56] ALA. CODE 1975 § 22-6-120(3).

necessary."[57] '"Medical Necessity' or 'Medically Necessary Care' means any health care service intervention, or supply (collectively referred to as 'service') that a physician . . . , exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing, or treating an illness, . . . injury, disease, condition, or its systems, in a manner that is . . . not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury, disease, or condition."[58]

55. In Alaska, the legislative purpose of the state's Medicaid program is to enable Medicaid recipients to receive "uniform and high quality care that is appropriate to their condition and cost-effective to the state."[59]

56. In Arizona, "[o]nly medically necessary, cost effective, and federally-reimbursable and state-reimbursable services are covered services" under the Medicaid program.[60]

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[57] Alabama Medicaid Provider Manual § 7.1, http://www.medicaid.alabama.gov/documents/6.0_Providers/6.7_Manuals/6.7.2_Provider_Manuals_2016/6.7.2.1_January_2016/Jan16_07.pdf; *see also id*. § 7.1.8 ("All services must be reasonable and necessary *in the specific case* and must meet the criteria of specific governing policies." (emphasis added)).

[58] *Id*. § 7.1.1.

[59] ALASKA STAT. ANN. § 47.07.010.

[60] ARIZ. ADMIN. CODE R9-22-202 (providing that this general requirement is "[i]n addition to other requirements and limitations specified in" the Medicaid regulations). Importantly, this cost-effectiveness limitation applies to pharmaceutical services. *See* ARIZ. ADMIN. CODE R9-22-101 (defining "covered

57. In Arkansas, "all services provided must be medically necessary," and services are "medically necessary"[61] only if "there is no other equally effective (although more conservative or less costly) course of treatment available or suitable for the beneficiary requiring the service."[62] It is under this purpose that the Alaskan legislature authorized the state to participate in Medicaid.[63]

58. In Colorado, the Medicaid program excludes from coverage items and services that are not medically necessary in the diagnosis or treatment of an illness or injury.[64] Medical necessity requires that the goods and services be "performed in a cost effective and most appropriate setting required by the client's condition."[65] Indeed, in Colorado, "practices that are inconsistent with sound fiscal business or medical practice, and result in an unnecessary cost . . . or overpayment . . . or in reimbursement for goods or services that are not medically

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services" to mean "the health and medical services described in Articles 2 and 12 of this Chapter); ARIZ. ADMIN. CODE R9-22-2209 (providing "pharmaceutical services under Article 2). *See also* ARIZ. ADMIN. CODE §§ R9-22-201 (defining "pharmaceutical services" to "include only" medically necessary medications that are prescribed by a physician").

[61] Ark. Medicaid Program Provider Manual, §§ 142.100, https://www.medicaid.state.ar.us/Download/provider/provdocs/Manuals/SectionI/Section_I.doc.

[62] *Id.* § 400 (Glossary), http://goo.gl/v9Ep5j (noting also that "[c]overage may be denied if a service is not medically necessary").

[63] *Id.*

[64] COLO. CODE REGS. § 2505-10:8.011.11.

[65] *Id.* § 2505-10:8.076.1.8.

necessary" is considered abuse, which can result in termination of a provider agreement.[66]

59. In Connecticut, the Medicaid program only pays for covered services and goods that are medically necessary.[67] "Medically necessary" services are those that are "not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results."[68]

60. In Delaware, prescription drugs covered under the Medicaid program are restricted to medically necessary products.[69] "Medically necessary" is defined to "be the least costly, appropriate, available health service alternative, and will represent an effective and appropriate use of program funds."[70]

61. In Florida, the Medicaid program only pays for medically necessary services.[71] In order to be medically necessary, a service must be "reflective of the

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[66] *Id.* §§ 2505-10:8.076.1.1.

[67] CONN. AGENCIES REGS. § 17b-262-342(12).

[68] *Id.* § 17b-259b.

[69] Del. Health and Soc. Servs. Div. of Medicaid & Med. Assistance, Del. Med. Assistance Program Gen. Policy, § 1.27.3.1 (2013), http://www.dmap.state.de.us/downloads/manuals/General.Policy.Manual.pdf.

[70] *Id.* § 13.0, Appendix H.

[71] FLA. STAT. § 409.905; *see also* FLA. ADMIN. CODE ANN. R. 59G-1.010(16) (stating that "for a health service to be covered under the Florida Medicaid program, it must also meet all other medical necessity criteria as defined in subsection 59G-1.010(166)" of the Florida Administrative Code).

level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available."[72]

62. In Georgia, the Medicaid program only covers medically necessary services.[73] For medical services to be considered "medically necessary" under the Georgia Medicaid program, "there must be no other effective and more conservative or substantially less costly treatment, service and setting available."[74]

63. In Hawaii, "[m]edical assistance payments should not be made for certain health services or items" that are "not considered by the department to be medically necessary" or unless "[t]he same or similar results may be obtained by another method at a reduced cost."[75] In addition, to be medically necessary under Hawaii's Medicaid statute, health interventions (specifically, including drugs) must be "the most cost-effective method available to address the medical condition."[76]

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[72] FLA. ADMIN. CODE ANN. 59G-1.010(166).

[73] Georgia Department of Community Health, Division of Medicaid, Part I Policies and Procedures for Medicaid/PeachCare for Kids, at IV-14 (§ 405), 2016 WL 2738894 (providing that "[t]he Division may deny any portion or all of a provider's claim for reimbursement [when] [t]he services provided have been determined to be medically unnecessary"); *id.* at IV-15 (§ 407(E)), 2016 WL 2738897 (providing that the "Division may recoup payments previously made to a provider . . . [when] [t]he services provided have been determined to be medically unnecessary").

[74] *Id.* at Definitions-6.

[75] HAW. CODE R. 17-1737-84(a)(4)-(5).

[76] HAW. CODE R. 17-1700.1-2.

64. In Idaho, the Medicaid program pays for prescription drugs deemed medically necessary.[77] Medical necessity means, in part, that there "is no other equally effective course of treatment available or suitable for the participant requesting the service which is more conservative or substantially less costly."[78]

65. In Iowa, services covered by the Medicaid program must be the "least costly type of service which would reasonably meet the medical need of the patient."[79]

66. In Kansas, the Medicaid program does not reimburse a provider for pharmacy services unless the service was medically necessary.[80] "Medical necessity" contemplates the service being cost effective.[81]

67. In Louisiana, the Medicaid program only pays for medically necessary goods, services, and supplies. "In order to be considered medically necessary, services must be . . . those for which no equally effective, more conservative, and less costly course of treatment is available or suitable for the recipient."[82]

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[77] IDAHO ADMIN. CODE R. 16.03.09.662(01).
[78] *Id*. at 16.03.09.011(16)(b).
[79] IOWA ADMIN. CODE R. 441-79.9(2)(d).
[80] KAN. ADMIN. REGS. §§ 30-5-63; 30-5-92(a) ("The medical services provided to program recipients shall include pharmacy services.").
[81] *Id*. § 30-5-58(ooo)(1)(E).
[82] LA. REV. STAT. ANN. §§46:437-11.

68. In Maine, the Medicaid program only pays for services that are "medically necessary and described in the *MaineCare Benefits Manual*."[83] "Medically Necessary services are those reasonable necessary medical and remedial services that are . . . MaineCare covered services . . . provided within the regulations of this Manual."[84] To become a covered service in accordance with the Manual, the intervention must be "the most cost-effective method available to address the medical condition."[85]

69. In Maryland, the Medicaid program pays for covered services "when these services are deemed to be medically necessary."[86] A service is "medically necessary" only if that service is "the most cost efficient service that can be provided without sacrificing effectiveness or access to care."[87]

70. In Massachusetts, the Medicaid program "will not pay a provider for services that are not medically necessary and may impose sanctions on a provider for . . . prescribing a service . . . where such service . . . is not medically necessary."[88] A service is "medically necessary" only if "there is no other medical

[83] CODE ME. R. tit. 10-144 Ch. 101, Ch. I,, § 1.06-1.
[84] *Id*. § 1.02-4(E).
[85] *Id*. § 1.06-4(D).
[86] MD. CODE REGS. § 10.09.67.01 (A).
[87] *Id*. § 10.09.62.01(B)(112)(c).
[88] 130 MASS. CODE REGS. 450.204.

service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly."[89]

71. In Michigan, the Medicaid program only provides reimbursement for "medically appropriate services,"[90] and "reimbursement is not made to those providers whose services, supplies, or equipment cost the program in excess of the reasonable value received."[91] Moreover, the Michigan Medicaid program is required by statute to be a "prudent buyer."[92] Thus, the program is only authorized to pay "for those services, supplies, or equipment that are needed or appropriate,"[93] and the program is required to "economize by minimizing costs."[94]

72. In Minnesota, in order to be covered by the Medicaid program, a health service must "(1) be medically necessary; (2) be appropriate and effective for the medical needs of the recipient; (3) meet quality and timeliness standards; (4) be the most cost-effective health service available for the medical needs of the recipient; [and] represent an effective and appropriate use of medical assistance funds," among other requirements.[95]

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[89] *Id.* §§450.204(A).
[90] MICH. COMP. LAWS ANN. § 400.111a(3)(a).
[91] *Id.* § 400.111a(3)(d).
[92] *Id.* § 400.111a(3)(e).
[93] *Id.* § 400.111a(4)(b).
[94] *Id.* § 400.111a(4)(c).
[95] MINN. R. 9505.0210

73. In Mississippi, the Division of Medicaid provides coverage for medically necessary services.[96] A requirement for medical necessity is that "there is no other effective and more conservative or substantially less costly treatment services and setting available.[97]

74. In Montana, the Medicaid program requires that prescribed drugs "may be only those that are medically necessary and that are the most efficient and cost-effective."[98]

75. In Nebraska, the Nebraska Medical Assistance Program, which governs Medicaid, covers prescribed drugs "when medically necessary and appropriate."[99] Medical necessity is defined such that the supplies must be "[r]endered in the most cost-efficient manner and type of setting appropriate for the delivery of the covered service."[100]

76. In Nevada, the Nevada Medicaid Pharmacy Services program pays for "medically necessary prescription services for eligible Medicaid recipients under the care of the prescribing practitioner."[101] Medical necessity is determined by considering the "[l]evel of service that can be safely and effectively furnished, and

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[96] MISS. ADMIN CODE §§ 23-200:5.1(A).
[97] *Id.* §§ 23-200:5.1(B).
[98] MONT. CODE ANN. §§ 53-6-101(9); 53-6-101(4)(h).
[99] 471 NEB. ADMIN. CODE Ch. 1-000, §§ 1-002.
[100] *Id*. §§ 1-002.02A(2).
[101] Nevada Medicaid Services Manual § 1200, http://goo.gl/mEqBIR (last visited Oct. 18, 2015).

for which no equally effective and more conservative or less costly treatment is available."[102]

77. In New Jersey, the Medicaid program provides "necessary medical care and services for qualified applicants."[103] To be considered a "medically necessary service[]," there must be "no other equally effective, more conservative or substantially less costly course of treatment available or suitable for the enrollee."[104]

78. In New Mexico, Medicaid services are provided by managed care organizations. Specifically, the New Mexico legislature has authorized the New Mexico Human Services Department to "provide for a statewide, managed care system to provide cost-efficient, preventative, primary and acute care for Medicaid recipients."[105] Given the statutory mandate, New Mexico Medicaid managed care organizations cannot properly cover the cost of services—including prescription drugs—that are not cost-efficient.

79. In North Carolina, the Medicaid program pays for "medically necessary and cost-effective care."[106]

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[102] *Id.* § 103.1.
[103] N.J. STAT. ANN. § 30:4D-5
[104] N.J. ADMIN. CODE § 10:74-1.4.
[105] N.M. STAT. ANN. § 27-2-12.6.
[106] N.C. Div. of Med. Assistance, Programs and Servs., https://www2.ncdhhs.gov/dmA/services/index.htm.

80. In Ohio, the Medicaid program provides that a medical service is reimbursable if it is medically necessary.[107] A "medically necessary" service must be "the lowest cost alternative that effectively addresses and treats the medical problem."[108]

81. In Oklahoma, the Medicaid program provides payment "only for services that are medically necessary and essential to the diagnosis and treatment of the patient's presenting problems."[109] Specifically, services "must be delivered in the most cost-effective manner and most appropriate setting."[110]

82. In Oregon, the Medicaid Program will "make no payment for any expense incurred for . . . services or items that are . . . [d]etermined not medically or dentally appropriate."[111] To be "medically appropriate," services and medical supplies must be "[t]he most cost effective of the alterative levels of medical services or medical supplies that can be safely provided to a Medicaid patient." [112] In Oregon, a Medicaid service is "cost-effective" if it is "the lowest cost health service or item that . . . meets the medical needs of the client.[113]

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[107] OHIO ADMIN. CODE §§ 5160-1-02(A)(1).
[108] *Id.* §§ 5160-1-01(C)(4).
[109] OKLA. ADMIN. CODE § 317:30-3-1(d).
[110] *Id.* § 317:30-3-1(f).
[111] OR. ADMIN R. 410-120-1200(2)(b).
[112] *Id.* R. 410-120-0000(127).
[113] *Id.* R. 410-120-1200(52).

83. In Rhode Island, "[t]he standard of 'medical necessity' is used as the basis for determining whether access to a Medicaid covered service[] is required and appropriate."[114] "Medically necessary services must be provided in the most cost-efficient and appropriate setting . . . ."[115]

84. In South Dakota, the Medicaid program requires that services be medically necessary.[116] To be medically necessary, there must be "no other equally effective course of treatment available or suitable for the recipient requesting the service which is more conservative or substantially less costly."[117]

85. In Tennessee, the Medicaid program provides participants with "only those medical items and services that are . . . medically necessary."[118] To be "medically necessary, a medical item or service must be recommended by a physician who is treating the enrollee and . . . must be the least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee."[119]

86. In Utah, the Medicaid program excludes from coverage services that are medically unnecessary or unreasonable.[120] "Medically necessary service" is

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[114] R.I. CODE R. 39-12:1310.06.
[115] *Id.*
[116] S.D. ADMIN. R. 67:16:01:06.02.
[117] *Id.* R. 67:16:01:06.02(5).
[118] TENN. CODE ANN. § 71-5-144(a)(2).
[119] *Id.* § 71-5-144(b)(3).
[120] UTAH ADMIN. CODE R. 414-10.

defined to mean that "there is no other equally effective course of treatment available or suitable for the recipient requesting the service that is more conservative or substantially less costly."[121]

87. In Washington, the Medicaid program pays only for services that are medically necessary.[122] "Medically necessary" is defined to mean that "[t]here is no other equally effective, more conservative or substantially less costly course of treatment available or suitable for the client requesting the service."[123]

88. In Wisconsin, the Medicaid program does not reimburse for services that are "medically unnecessary, inappropriate, in excess of accepted standards of reasonableness or less costly alternative services, or of excessive frequency or duration."[124]

89. In Wyoming, the Medicaid program covers drugs if medically necessary.[125] Medical necessity is defined as a service "[p]erformed in the most cost effective and appropriate setting required by the client's condition."[126]

90. BMS/Sanofi's misrepresentations about the efficacy of Plavix when compared to aspirin deprived physicians of the opportunity to make the "cost-effectiveness" assessment based on accurate information. As a result of their

[121] *Id.* at 414-1-2 (18).
[122] WASH. ADMIN. CODE § 182-501-0050(4)(d).
[123] *Id.* § 182-500-0070.
[124] WIS. ADMIN. CODE HS § 107.02(2).
[125] WYO. ADMIN. CODE §§ HLTH MDCD Ch. 26 § 5.
[126] *Id.* §§ HLTH MDCD Ch. 1 § 3(cli)(D).

misrepresentation, BMS/Sanofi caused numerous physicians to prescribe Plavix when Plavix was not cost effective, and therefore, not covered by Medicaid. And where Plavix is on a formulary, these false certifications that Plavix met the requirements for Medicaid coverage directly caused the reimbursement of false claims by Government Payors.

91. Therefore, BMS/Sanofi caused physicians and pharmacists to submit false claims to the federal government and state programs under Medicaid; the governments paid those false claims and are now entitled to recover damages and civil penalties.

D. BMS/Sanofi Caused the Submission of False Claims by Fraudulently Inducing Formulary Committees to Include Plavix on the State Formularies when Plavix did not Meet Formulary Requirements

92. Congress has imposed strict requirements on Medicaid drug coverage. In order for the cost of a drug to be reimbursed under Medicaid, the drug manufacturer must have entered into, and have in effect, a rebate agreement wherein the manufacturer agrees to give the applicable Government Payor back a percentage of the cost of the reimbursed drug.[127] Drugs that are covered by a rebate agreement are then statutorily divided into two distinct categories: those that require prior authorization from Medicaid prior to reimbursement and those that

[127] *See* 42 U.S.C. § 1396r-8(a)(1).

are reimbursed automatically when the drug is prescribed.[128] To make clear to the public the drugs that do not require prior authorization, each state maintains a formulary or preferred drug list (referred to in this Complaint as a "formulary") that explicitly exempts certain Medicaid-eligible drugs from a prior authorization requirement. Medicaid is obligated to provide reimbursement for the cost of a drug on a state's formulary when the drug is prescribed by a physician for an "on-label" indication. Because the formulary bypasses all pre-approval requirements for reimbursement (other than a physician's prescription), drug companies receive substantial economic benefits when one of their drugs is placed on a state's formulary.[129]

93. Each state's formulary is "developed by a committee consisting of physicians, pharmacists, and other appropriate individuals" appointed by the Governor of the State.[130] This committee has the statutory power to exclude drugs from the formulary. Federal law, for example, provides that a drug may be excluded if the drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment

[128] *Id*. § 1396r-8(d)-(e).

[129] For example, the North Carolina Division of Medial Assistance encourages prescribers "to write prescriptions for 'preferred' (PDL) products." N.C. Medical Assistance Health and Human Services, Outpatient Pharmacy Servs., http://dma.ncdhhs.gov/providers/programs-services/Prescription-drugs/Outpatient-Pharmacy-Services.

[130] *Id.* § 1396-r-8(d)(4)(A).

for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion."[131] In addition, the committee may exclude drugs "in order to achieve program savings consistent with protecting the health of program beneficiaries."[132] Thus, according to federal law, states may exclude even an on-label outpatient drug if the drug does not have a meaningful advantage in terms of cost and effectiveness.[133]

94. The persons that constitute each state's formulary committee are the very same types of persons that received BMS/Sanofi's false and misleading information about Plavix—physicians and pharmacists. For example, when BMS/Sanofi sought to have Plavix added to the Idaho formulary, the Idaho formulary committee—composed of physicians, nurses, and pharmacists—held a committee meeting to consider whether to include Plavix on the formulary.[134] A representative from Sanofi, Mark Haumschild, addressed the committee during the public comment period.[135] Consistent with Relator's allegations that BMS/Sanofi trained its sales representatives to misrepresent the cost effectiveness of Plavix,

[131] 42 U.S.C. § 1396r-8(d)(4)(C).
[132] *Id.* § 1396r-8(d)(4)(E).
[133] *See id.*
[134] *See* Pharmacy and Therapeutics Committee Meeting Record (July 15, 2005), http://goo.gl/fpjdJY (last visited Aug. 8, 2016).
[135] *Id*. at 3 (noting that the "Committee recommended that Ticlopidine, Aggrenox, and Plavix be designated as preferred agents.".

Mr. Haumschild devoted his public comment time to misleading the formulary committee.

95. Specifically, Mr. Haumschild discussed the CAPRIE trial—"a comparison of Plavix to aspirin"—and informed the formulary committee that the trial demonstrated that Plavix "*was more effective than aspirin* in long term administration up to three years to reduce thrombotic events."[136] Notably, BMS/Sanofi had been advised by the FDA four years previously that such superiority claims were unsubstantiated.[137] Indeed, the FDA told BMS/Sanofi to cease making such representations.[138]

96. Based on this information, the committee approved Plavix for inclusion on the formulary. Given the overarching goal of Idaho's formulary—to "provide quality care to Medicaid participants *with the most effective drug at the right price*"[139]—the formulary committee would not have been authorized to include Plavix on Idaho's formulary had it known the truth about Plavix.

97. To comply with cost-effectiveness requirements for Medicaid coverage and the conditions of placement on the formulary, each Cost-Imposed state's Medicaid program would have had no choice but to exclude Plavix from the

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[136] *Id*. at 10.
[137] Ex. P (May 9, 2001 Letter) at 1.
[138] *Id*. at 2.
[139] Idaho Department of Health and Welfare, Prescription Drugs, http://healthandwelfare.idaho.gov/Medical/PrescriptionDrugs/tabid/119/default.aspx (emphasis added).

formulary had the state known the truth about Plavix—that it is extraordinarily more expensive than aspirin and no more effective for certain indications. BMS/Sanofi, however, mislead the states into believing that Plavix was more effective than aspirin for certain indications even though it was not.

98. The Third Circuit also has recognized that, even when a fraudulent misrepresentation is not made as part of a certification of a claim for payment, it can be actionable under the FCA where a knowingly false or fraudulent material statement caused the government to pay out or to forfeit money due.[140] Placement of a drug on a state's formulary obligates the state to pay for the drug if prescribed in accordance with the formulary. A state's inclusion of a drug on its formulary signifies to the medical community—physicians, pharmacists, and patients—that it agrees to pay for the drug if it is prescribed for certain indications. Thus, representations to the state about a drug for inclusion on the formulary are consequential. They have a material impact on the ultimate payment of claims under Medicaid. False misrepresentations to a formulary committee give rise to liability under the FCA, even if a claim for payment was legally true at the time it was made.

99. Here, BMS/Sanofi's misrepresentations about the cost effectiveness of Plavix (particularly that it was more effective than aspirin for certain indications)

[140] *See U.S. ex rel. Thomas v. Siemens AG*, 593 Fed. Appx. 139, 143 (3d Cir. 2014).

to the formulary committees fraudulently induced states to include Plavix on their respective formulary. These material misrepresentations put states in the inequitable position of being obligated to pay for Plavix when prescribed in accordance with the formulary, even though Plavix is 100 times more expensive than aspirin and not any more effective for certain uses. BMS/Sanofi's fraudulent and misleading conduct before the state formulary committees resulted in an obligation of each state's Medicaid program to reimburse Plavix when prescribed, even when Plavix was not cost effective, and therefore, not properly on the state formulary. BMS/Sanofi should not be permitted to enjoy the benefits of the formulary that it procured by fraud.

100. As detailed below, at least 47 of the states and the District of Columbia consider cost-effectiveness when evaluating a drug for inclusion on the state formulary (also known, for the purposes of this Complaint, as a preferred drug list).[141]

101. In Alabama, the law requires "[t]he Medicaid Pharmacy and Therapeutics Committee [to] develop its preferred drug list recommendations by

[141] Based on information and belief, Kentucky and South Carolina consider cost-effectiveness when evaluating a drug for inclusion on the state formulary. Based on information and belief, North Dakota did not develop a preferred drug list until 2016. *See* Health Information Designs, North Dakota PDL, http://www.hidesigns.com/ndmedicaid/pdl/ (showing PDL that considered only a single drug class in 2015; the first PDL to consider more than one class was effective in Jan. 2016).

considering the clinical efficacy, safety, and cost effectiveness of a product."[142] Clopidogrel[143] is on its preferred drug list.[144] Upon information and belief, Alabama would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

102. In Alaska, the Pharmacy and Therapeutics Committee is appointed by the Commissioner to review pharmaceutical classes to identify drugs that are clinically and therapeutically equivalent, and have a potential cost savings over other drugs in the same class.[145] The Alaska formulary, therefore, identifies "both clinically sound and cost effective medications for use" by Medicaid participants.[146] Clopidogrel is a preferred drug on Alaska's Medicaid formulary.[147] Upon information and belief, Alaska would not have included Plavix on its

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[142] ALA. CODE 1975 § 22-6-122(b); *see also* Ala. Code. § 22-6-123(a) ("Drugs will be considered for the Medicaid preferred drug list based on clinical efficacy, side effect profiles, appropriate usage, and cost effectiveness.").

[143] Up until 2012, Plavix enjoyed patent protection over clopidogrel and there were no generic versions available on the market. Therefore, for purposes of this action, clopidogrel being on the list is equivalent to Plavix.

[144] Ala. Medicaid Agency PDL Reference Tool, http://medicaid.alabama.gov/documents/4.0_Programs/4.5_Pharmacy_Services/4.5.12_PDL/4.5.12_PDL_Ref_Tool_Revised_7-9-13.pdf.

[145] Alaska Dept. of Health & Social Servs. Pharmacy & Therapeutics Comm. Procedures, http://dhss.alaska.gov/dhcs/Documents/pdl/downloads_docs/P_T_Procedures.pdf.

[146] *Id*.

[147] Alaska Medicaid Preferred Drug List, http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/2012PDL.pdf.

preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

103. In Arizona, the Pharmacy and Therapeutics Committee evaluates drugs by reviewing safety, efficacy, and other information.[148] The review process continually promotes the most cost-effective agents.[149] Clopidogrel is on Arizona's Medicaid approved drug list.[150] Upon information and belief, Arizona would have excluded Plavix from its Medicaid approved drug list, and would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

104. In Arkansas, the Arkansas Drug Review Committee reviews several factors to recommend drugs to the Department of Health and Safety, including the net cost to the state.[151] Upon information and belief, clopidogrel is on the preferred drug list.[152] Upon information and belief, Arkansas would have excluded

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[148] AHCCCS Fee-For-Service Program Drug List, http://www.bridgewayhs.com/files/2010/02/AHCCCS-Fee-for-Service-Drug-List-Duals.pdf.

[149] *Id*.

[150] AHCCCS Drug List, https://www.azahcccs.gov/Resources/Downloads/PharmacyUpdates/AHCCCSDrugListJuly12016FINAL.pdf.

[151] Program Overview for Ark. Medicaid Evidence-based Prescription Drug Program, https://www.medicaid.state.ar.us/Download/provider/pharm/ProgramOverview.pdf.

[152] *See* Ambetter of Arkansas, 2016 Prescription Drug List, https://www.ambetterofarkansas.com/content/dam/centene/Ambetter%20of%20Ar

Plavix from the preferred drug list, and would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

105. In California, the Medi-Cal Contract Drug Advisory Committee evaluates drugs by looking at, among other things, the safety, effectiveness, essential need, and cost of the drug.[153] Upon information and belief, Plavix was an preferred drug on the Medi-Cal contract drug list. Notably, from December 1, 2008 through November 30, 2009, Medi-Cal covered 70,055 clopidogrel claims, representing 12,527 recipients.[154] Upon information and belief, California would have excluded Plavix from its Medicaid contract drug list, and would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

106. In Colorado, the Pharmacy and Therapeutics Committee reviews drugs for inclusion on the Colorado Preferred Drug list based on safety and efficacy.[155] After the Committee evaluates the efficacy of a particular drug, the

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kansas/PDFs/FORMULARY-AMBETTER_OF_ARKANSAS.pdf (listing Clopidogrel as a "preferred" drug).

[153] Medi-Cal Drug Review Policy & Procedures, http://web.law.columbia.edu/sites/default/files/microsites/attorneys-general/files/Medi-Cal_Drug_Review_Policy_and_Procedures.pdf

[154] Medi-Cal, Clopidogrel and Omeprazole – A Drug Interaction of Importance, https://files.medi-cal.ca.gov/pubsdoco/dur/articles/dured_11255.asp (noting that clopidogrel is a "commonly used" drug).

[155] 10 COLO. CODE REGS. § 2505-10:8.800.17.C.1.

Colorado Department of Health Care Policy and Financing makes recommendations to the Colorado Medical Director considering the Committee's efficacy evaluation and the "cost-effectiveness" of the particular drug.[156] Clopidogrel is a preferred drug.[157] Upon information and belief, Colorado would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

107. In Connecticut, the Pharmaceutical and Therapeutics Committee considers "clinical efficacy, safety and cost effectiveness of a product" when creating the Medicaid preferred drug list.[158] Clopidogrel is a preferred drug.[159] Upon information and belief, Connecticut would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

108. In Delaware, the Pharmaceutical and Therapeutics Committee selects its preferred drug list by reviewing the "relative clinical effectiveness and cost of

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[156] *Id*. § 2505-10:8.800.16.

[157] Colo. Dept. of Health Care Policy & Financing, Preferred Drug List, https://www.colorado.gov/pacific/sites/default/files/PDL%20effective%20January%201%202015.pdf.

[158] CONN. GEN. STAT. § 17b-274d(i).

[159] Conn. Medicaid Alphabetized Preferred Drug List, https://www.ctdssmap.com/CTPortal/Portals/0/StaticContent/Publications/CT_PDL_alpha.pdf.

products . . . ."[160] The objective is to "achieve quality pharmaceutical care for recipients enrolled in the Department's Medicaid programs while providing significant state savings."[161] Clopidogrel is a preferred agent.[162] Upon information and belief, Delaware would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

109. In the District of Columbia, the Department of Health Care Finance Policy Pharmacy and Therapeutics Committee reviews drugs and receives comments from interested parties in order to make recommendations for the preferred drug list.[163] The Government of the District of Columbia, Department of Health, Medical Assistance Administration implemented its Medicaid preferred drug list to "provide cost effective and safe drug therapy for District of Columbia Medicaid recipients."[164] Indeed, when the Department of Health implemented the District of Columbia preferred drug list in 2007, it did so to "help the Department

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[160] Del. Med. Assistance Program, http://www.dmap.state.de.us/information/pharmacy.html.

[161] *Id*.

[162] Del. Med. Assistance Program Preferred Drug List, http://www.dmap.state.de.us/information/Pharmacy/DEM%20PDL.pdf.

[163] *See, e.g.*, Dept. of Health Care Fin., Pharmacy & Therapeutics Comm. Meeting Agenda, Sept. 5, 2013, https://dc.fhsc.com/downloads/providers/DCRx_PT_agenda_20130905.pdf.

[164] *See* Memorandum from Government of District of Columbia, Department of Health to Carolyn Rachel-Price, Subject: District of Columbia Fee-for-Service Medicaid Preferred Drug List (Mar. 14, 2007), https://dc.fhsc.com/downloads/providers/DCRx_memo_provider_20070314.pdf

maintain quality and cost-effectiveness in its pharmacy benefit program."[165] Clopidogrel is a preferred drug.[166] Upon information and belief, D.C. would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

110. In Florida, the Pharmacy and Therapeutics Committee selects the Florida Medicaid Preferred Drug List by choosing cost effective choices and informs clinicians of effective products that provide favorable net costs to Medicaid.[167] The Florida Medicaid PDL "shall be a list of cost-effective, safe and clinically efficient medications for each of the therapeutic classes on the list."[168] Clopidogrel is on the preferred drug list.[169] Upon information and belief, Florida would not have included Plavix on its Medicaid Preferred Drug List, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

111. In Georgia, the Georgia Drug Utilization Review Board serves as a Pharmacy and Therapeutics Committee and advises the Department about products

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[165] *Id.*

[166] D.C. Dept. of Health Care Fin., https://dc.fhsc.com/downloads /providers/DCRx_PDL_listing.pdf.

[167] AHCA Medicaid Pharm. & Therapeutics Comm., http://ahca.myflorida. com/medicaid/Prescribed_Drug/pharm_thera/index.shtml.

[168] *Id.*

[169] Fla. Medicaid Preferred Drug List, http://ahca.myflorida.com/ medicaid/Prescribed_Drug/pharm_thera/pdf/PDL_07-18-16.pdf.

considered to be the most clinically effective for Medicaid, in an attempt to identify the most cost-effective policies for its members.[170] Clopidogrel is a preferred drug.[171] Upon information and belief, Georgia would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

112. In Hawaii, the Pharmacy and Therapeutics Committee chooses drugs for its Medicaid Drug Formulary based on "efficacy, safety, and economy from manufacturers" that participate in the rebate program.[172] Plavix is on the Preferred Drug List.[173] Upon information and belief, Hawaii would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

113. In Idaho, the Idaho Medicaid Pharmacy and Therapeutics Committee makes recommendations for medication coverage of specific drug classes to the

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[170] Ga. Dept. of Cmty. Health Drug Utilization Review Board, http://dch.georgia.gov/drug-utilization-review-board.

[171] Ga. Medicaid/PeachCare Preferred Drug List, http://dch.georgia.gov/sites/dch.georgia.gov/files/PDL%20by%20Drug%20Name%20-%20Effective%20%209.1.13.pdf.

[172] Chapter 19, Medicaid Provider Manual, http://www.med-quest.us/PDFs/Provider%20Manual/PMChp1911.pdf.

[173] Ohana Medicaid Comprehensive Preferred Drug List, https://www.ohanahealthplan.com/WCAssets/corporate/assets/MCD_OHANA_PDL.pdf.

Idaho Department of Health and Welfare based primarily on evaluations of the relative safety, effectiveness, and clinical outcomes of a specific medication in comparison with other therapeutically interchangeable alternative medications.[174] The overarching goal of the Idaho Medicaid Pharmacy Program "is to provide quality care to Medicaid participants with the most effective drug at the right price."[175] Upon information and belief, Idaho would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

114. In Illinois, "the Illinois Department of Healthcare and Family Services (HFS) maintains a preferred drug list (PDL) in order to promote clinically appropriate utilization of pharmaceuticals in a cost-effective manner."[176] If a drug under consideration has no "therapeutic advantage" in terms of "safety, effectiveness, and clinical outcomes," then "HFS considers the net economic

[174] Idaho Medicaid Pharmacy & Therapeutics Comm., http://healthandwelfare.idaho.gov/Portals/0/Medical/PrescriptionDrugs/PNT%20Publictestimony%20ver1111b%20_3_.pdf.

[175] Idaho Department of Health and Welfare, Prescription Drugs, http://healthandwelfare.idaho.gov/Medical/PrescriptionDrugs/tabid/119/default.asp.

[176] Illinois Department of Healthcare and Family Services, PDL Background, https://www.illinois.gov/hfs/MedicalProviders/Pharmacy/Pages/PDLBackground.aspx.

impact of such drugs when recommending drugs for inclusion in the PDL."[177] Upon receipt of clinical recommendations, the department, in consultation with pharmacologists, pharmacists, and physicians, develops its PDL recommendations taking into account both clinical and cost factors."[178] The Illinois PDL "has proven a very effective tool in addressing the escalating cost of drugs."[179] Clopidogrel is a preferred drug.[180] Upon information and belief, Illinois would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

115. In Indiana, the Medicaid preferred drug list is developed by giving consideration to the efficacy of drugs, and includes cost effectiveness considerations in the decision.[181] The list is developed and maintained by the Drug Utilization Review (DUR) Board. The Board designates drugs as preferred or non-preferred "based on clinical and financial considerations."[182] Plavix is a preferred

[177] *Id.*
[178] *Id.*
[179] *Id.*
[180] Preferred Drug List, Ill. Medicaid, https://www.illinois.gov/hfs/SiteCollectionDocuments/20160701_FINAL.pdf.
[181] Ind. 2002 Senate Bill 228.
[182] Indiana Medicaid Preferred Drug List (PDL), https://inm.rxportal.mycatamaranrx.com/rxclaim/INM/20160801_INM_PDL(2).pdf

drug.[183] Upon information and belief, Indiana would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

116. In Iowa, the Pharmaceutical and Therapeutics Committee develops the Medicaid preferred drug list by evaluating relative cost of each product and compared products with the same class to identify the most clinically effective, and cost efficient product.[184] Clopidogrel is on the list.[185] Upon information and belief, Iowa would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

117. In Kansas, the Kansas Medical Assistance Program "has created a preferred drug list (PDL) to promote clinically appropriate utilization of pharmaceuticals in a cost-effective manner without compromising the quality of

[183] Indiana Medicaid Preferred Drug List (PDL), https://inm.rxportal.mycatamaranrx.com/rxclaim/INM/Downloads/Master%20Preferred%20Drug%20List%20updated%2001-01-2012.pdf.

[184] Iowa Medicaid Advisory Grps., http://www.ime.state.ia.us/IMEAdvisoryGroups.html.

[185] Dept. of Human Servs. Iowa Medicaid Program, http://www.iowamedicaidpdl.com/sites/default/files/ghs-files/preferred-drug-lists/2013-09-03/rt44632final20130830v2.pdf.

care."[186] Drugs are evaluated on the basis of safety, effectiveness and clinical outcomes, but if there is no therapeutic advantage (as is the case with Plavix as compared to aspirin for certain indications), then the Kansas department of health and environment "shall consider the cost effectiveness and the net economic impact of such drugs in making recommendations for inclusion in the state medicaid preferred drug formulary."[187] Plavix is on the preferred drug list.[188] Upon information and belief, Kansas would have excluded Plavix from Medicaid coverage but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

118. In Kentucky, Pharmacy and Therapeutics Advisory Committee advises the governor, secretary of the Cabinet for Health and Family Services and the commissioner of the Department for Medicaid Services on development and administration of an outpatient drug formulary.[189] On information and belief, the Pharmacy and Therapeutics Advisory Committee considers cost-effectiveness when evaluating a drug for inclusion on the state formulary. Clopidogrel is on the

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[186] Kan. Dept. of Health & Env't, Preferred Drug List (PDL), http://www.kdheks.gov/hcf/pharmacy/pharmacy_druglist.html.

[187] KAN. STAT. ANN. § 39-7,121a.

[188] KanCare, Preferred Drug List, http://www.kdheks.gov/hcf/pharmacy/download/PDLList.pdf.

[189] *See* Pharmacy & Therapeutics Advisory Comm., http://chfs.ky.gov/dms/pt.htm.

formulary / preferred drug list.[190] Upon information and belief, Kentucky would not have included Plavix on its Medicaid formulary, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

119. In Louisiana, the legislature authorized the Department of Health and Hospitals to "establish a drug list that utilized a prior approval process or any other process or combination of processes that prove to be cost-effective in the medical assistance program."[191] When a new drug is approved by the FDA, the Louisiana "Medicaid Pharmaceutical and Therapeutics Committee shall conduct an evidence-based analysis of the drug to determine if the drug shall be maintained on the formulary. The analysis shall include but not be limited to the medical evidence of the clinical effectiveness of the drug as well as evidence of the cost-effectiveness of the drug in treating illness and disease. The determination by the committee on any new drug approved by the United States Food and Drug Administration shall be made no later than ninety days after the drug becomes commercially available. Prior to the drug being prior authorized, it must have been reviewed by the Medicaid Pharmaceutical and Therapeutics Committee."[192] Plavix is on the

[190] Kentucky Pharmacy Preferred Drug List, https://kyportal.magellanmedicaid.com/public/client/static/kentucky/documents/PreferredDrugGuide_full.pdf.

[191] La. Stat. Ann. § 46:153.3(B)(2)(a).

[192] *Id*. § 46:153.3(D)(5)(b).

formulary.[193] Upon information and belief, Louisiana would not have included Plavix on its Medicaid formulary, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

120. In Maine, the Drug Utilization Review (DUR) Committee "[r]eview[s] new drugs for Preferred Drug List (PDL) status and make[s] determinations no later than six (6) months after their entry onto the market." "In making a determination of PDL status, the DUR committee shall consider whether a new drug is: (i) therapeutically equivalent or superior to existing preferred or non-preferred choices; and (ii) is safe or safer than existing preferred or non-preferred choices; and (iii) whether the net cost, adjusted for rebates, is less expensive than all existing PDL choices."[194] Clopidogrel is on Maine's PDL.[195] Upon information and belief, Maine would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

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[193] Preferred Drug List / Prior Authorization List, http://www.lamedicaid.com/provweb1/pharmacy/preferred_list.htm.

[194] CODE ME. R. tit. 10-144 Ch. 101, Ch. II,, § 80.04-1(F)(5)(b).

[195] MaineCare PDL, http://www.mainecarepdl.org/sites/default/files/ghs-files/pdl/2013-07-05/copy-ssdc-pdlmaine-without-criteria-june2013-1.pdf.

121. In Maryland, the Pharmacy and Therapeutics Committee "reviews classes of medications and recommends to [the Department of Health and Mental Hygiene] which medications should be included in the Preferred Drug List for prescribing to Medicaid recipients. The Preferred Drug List is composed of cost-effective, medically appropriate drug therapies for Medicaid recipients."[196] The Committee is required to "develop its Preferred Drug List recommendations by considering the clinical efficacy, safety, and cost effectiveness of drug products."[197] The Pharmacy & Therapeutics Committee makes recommendations about the pharmacy preferred drug list in part by hearing public testimony from speakers inside the drug industry.[198] Plavix is listed as a preferred drug.[199] Upon information and belief, Maryland would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

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[196] Maryland Register – General Notices – Department of Health and Mental Hygiene, *Call for Psychiatrist Nomination*, http://hcregs.bna.com/cgi-bin/hcstate?mdgn016a257 (Sept. 14, 2007).

[197] *Id.*

[198] *See* Md. Medicaid Pharmacy Preferred Drug List, https://mmcp.dhmh.maryland.gov/pap/Pages/Public-Meeting-Announcement-and-Procedures-for-Public-Testimony.aspx.

[199] Md. Preferred Drug List, http://www.providersynergies.com/services/documents/MDM_PDL.pdf.

122. In Massachusetts, the Drug Utilization Board determines which drugs to put on the MassHealth Drug List by looking on safety, effectiveness, and cost.[200] Clopidogrel is on the list.[201] Upon information and belief, Massachusetts would not have included Plavix on its Medicaid MassHealth Drug List, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

123. In Michigan, the Governor established the Pharmacy and Therapeutics Committee to oversee a preferred drug list in order to "provide the greatest possible access to cost effective prescription drug coverage for all of its citizens."[202] The Michigan Pharmacy and Therapeutics Committee recommends to the Department guidelines for prescription drugs.[203] The Committee makes "recommendations to the department for the inclusion of prescription drugs on the preferred drug list based on available information regarding the known potential impact on patient are, the known potential fiscal impact on related Medicaid

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[200] Health & Human Servs., Introduction to MassHealth Drug List, https://masshealthdruglist.ehs.state.ma.us/MHDL/pubintro.do?category=Introduction+to+MassHealth+Drug+List.

[201] Health & Human Servs., MassHealth Drug List A-Z, https://masshealthdruglist.ehs.state.ma.us/MHDL/pubsearch.do?index=C.

[202] Executive Order 2001-8, Michigan Pharmacy and Therapeutics Committee, Michigan Department of Community Health, http://www.michigan.gov/formergovernors/0,4584,7-212-31303_31305-3609--,00.html.

[203] Mich. Pharmacy & Therapeutics Comm., http://www.michigan.gov/snyder/0,1607,7-277-57738_57679_57726-250198--,00.html.

covered services, and sound clinical evidence found in labeling, drug compendia, and peer-reviewed literature pertaining to use of the drug in the relevant population."[204] Clopidogrel is a preferred agent.[205] Upon information and belief, Michigan would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

124. In Minnesota, the Drug Formulary Committee reviews and recommends which drugs require additional prior-authorization and drugs which are placed on the state preferred drug list.[206] The preferred drug list is "a list of prescription drugs within designated therapeutic classes selected by the commissioner, for which prior authorization based on the identity of the drug or class is not required."[207] In determining whether a drug can be placed on the preferred drug list, the Formulary Committee considers "the impact that placing the drug on prior authorization may have on the quality of patient care and on program costs."[208] Clopidogrel is on the list.[209] Upon information and belief, Minnesota would not have included Plavix on its Medicaid preferred drug list, and

[204] Mich. Comp. Laws. Ann. § 333.9707(a).
[205] Mich. Dept. of Cmty. Health Preferred Drug List, https://michigan.fhsc.com/Downloads/PDL_20160714c.pdf.
[206] Minn. Stat. Ann. § 256B.0625, subd. 13f.
[207] *Id*. § 256B.0625, subd. 13g.
[208] *Id*. § 256B.0625, subd. 13f.
[209] Minn. Fee-for-Service Medicaid Preferred Drug List,

instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

125. In Mississippi, the Mississippi Division of Medicaid's Pharmacy and Therapeutics Committee assesses drugs' "safety, efficacy, and overall cost value" to recommend drugs for preferred status on the Division of Medicaid's Preferred Drug List and/or drugs for prior authorization.[210] Drugs designated as preferred on the Preferred Drug list are "selected for their efficaciousness, clinical significance, cost effectiveness and safety for Medicaid beneficiaries."[211] Mississippi included Plavix on its preferred drug list.[212] Upon information and belief, Mississippi would have excluded Plavix from its preferred drug list, and would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

126. In Missouri, the Missouri HealthNet Preferred Drug List is a list of preferred drugs that the agency would like prescribers to use[213] "[i]n an effort to ensure economic and efficient provision of the MO HealthNet pharmacy

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[210] *See* Miss. Div. of Medicaid Pharmacy and Therapeutics Committee, https://medicaid.ms.gov/providers/pharmacy/pharmacy-and-therapeutics-committee/.

[211] *See* Miss. Div. of Medicaid Preferred Drug List, https://medicaid.ms.gov/providers/pharmacy/preferred-drug-list/.

[212] Mississippi Division of Medicaid Preferred Drug List, Effective Jan. 1, 2012, https://medicaid.ms.gov/wp-content/uploads/2014/04/PreferredDrugList010112.pdf.

[213] Mo. HealthNet Preferred Drug List, FAQ, http://dss.mo.gov/mhd/faq/pages/faqpdl.htm.

benefit."[214] Specifically, the Preferred Drug List is "designed to enhance patient care and optimize the use of program funds through therapeutically prudent use of pharmaceuticals."[215] Drug manufactures must provide supplemental rebates in order to have a drug placed on Missouri's Preferred Drug List.[216] Clopidogrel is a preferred agent.[217] Upon information and belief, Missouri would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

127. In Montana, the Medicaid Drug Formulary Committee governs the Medicaid drug programs and established a preferred drug list of selected drugs that "have a significant clinical benefit over other agents in the same therapeutic class and also represent good value to the department based on total cost."[218] Clopidogrel is a preferred agent.[219] Upon information and belief, Montana would not have included Plavix on its Medicaid preferred drug list, and instead would

[214] State of Missouri, Pharmacy Manual § 13.6B(4), http://manuals.momed.com/collections/collection_pha/print.pdf.

[215] MO. CODE REGS. ANN. tit. 13, § 70-20.340(6).

[216] MO. CODE REGS. ANN. tit. 13, § 70-20.200(1)(D).

[217] Mo. Pharmacy Program – Preferred Drug List, http://dss.mo.gov/mhd/cs/pharmacy/pdf/anticoagulant-agents-pdl.pdf.

[218] MONT. CODE ANN. § 37.86.1102.

[219] Mont. Medicaid Preferred Drug List, https://medicaidprovider.mt.gov/Portals/68/docs/current/mtpdlcurrent.pdf.

have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

128. In Nebraska, the Pharmaceutical and Therapeutics Committee determines which drugs to but on the Preferred Drug List by looking at clinical effectiveness, and when drugs are equivalent or nearly equivalent, considering the cost.[220] Clopidogrel is a preferred drug.[221] Upon information and belief, Nebraska would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

129. In Nevada, a committee of physicians and pharmacists determines which drugs to put on Nevada Medicaid's Preferred Drug List by looking for clinically effective and safe drugs for the best available price.[222] Plavix is on the list.[223] Upon information and belief, Nevada would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from

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[220] Preferred Drug List Guidelines, https://nebraska.fhsc.com/Downloads/NE_PT_PDLguidelines-20100701.pdf.

[221] Neb. Medicaid Preferred Drug List, https://nebraska.fhsc.com/downloads/PDL/NE_PDL.pdf.

[222] *See* Intro. of Nev. Medicaid Preferred Drug List Program for Pharmacy Servs., http://www.medicaid.nv.gov/Downloads/provider/PDL_Notification.pdf.

[223] Nev. Medicaid Preferred Drug List, http://www.medicaid.nv.gov/Downloads/provider/NV_PDL_20111102.pdf. After Plavix lost its patent protection, Nevada switched it to a non-preferred agent, but still lists Clopidogrel as a preferred drug. https://www.medicaid.nv.gov/Downloads/provider/NV_PDL_20130805.pdf.

Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

130. In New Hampshire, the Drug Review Board recommends drugs for inclusion on the Medicaid preferred drug list based on safety and efficacy, and then based on cost.[224] In addition, the New Hampshire Department of Health and Human Services is authorized to take actions in managing the preferred drug list to "enhance efficiency, reduce the cost of prescription drugs, and maximize the benefits to the programs and enrollees."[225] Clopidogrel is on the list.[226] Upon information and belief, New Hampshire would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

131. New Jersey Medicaid uses a managed care system, where clients enroll in an HMO.[227] Aetna,[228] Horizon NJ Health,[229] Amerigroup NJ,[230]

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[224] Preferred Drug List, http://www.dhhs.nh.gov/ombp/pharmacy/preferred.htm.

[225] N.H. Rev. Stat. Ann. § 161-L:2.

[226] N.H. Dept. of Health and Human Servs. Preferred Drug List, http://www.dhhs.nh.gov/ombp/pharmacy/documents/preferred.pdf.

[227] N.J. Medicaid & Managed Care, http://www.state.nj.us/humanservices/dmahs/info/resources/care/.

[228] Aetna Better Health of New Jersey Formulary, https://www.aetnabetterhealth.com/newjersey/assets/pdf/ABHNJ_August%202016%20PDL.pdf.

UnitedHealthcare Community Plan,[231] and WellCare[232] list Clopidogrel or Plavix on their formularies. The UnitedHealthcare Preferred Drug list, for example, provides that the drugs listed on its PDL have been reviewed and approved by the Pharmacy and Therapeutics Committee and that "[t]he drugs have been selected to provide the most clinically appropriate and cost-effective medications for patients who have their drug benefit administered through UnitedHealthcare Community Plan." Similarly, the Amerigroup J Preferred Drug List states that "[t]he medications included in the PDL are reviewed and approved by the Pharmacy and Therapeutics Committee, which includes practicing Physicians and Pharmacists from the Amerigroup provider community. The goal of the PDL is to provide cost-effective pharmacotherapy choices, based on prospective, concurrent and retrospective review of medication therapies and utilization."[233] Upon information and belief, the New Jersey plans would not have included Plavix on their Medicaid preferred drug lists, and instead would have excluded Plavix from Medicaid

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[229] Horizon NJ Health, Prescription Drug Listing, http://www.horizonnjhealth.com/sites/default/files/formulary_english.pdf.

[230] Amerigroup NJ Preferred Drug List, https://providers.amerigroup.com/AGP%20Documents/NJNJ_CAID_PDL.pdf.

[231] UnitedHealthcare Preferred Drug List (PDL), New Jersey, https://www.uhccommunityplan.com/content/dam/communityplan/plandocuments/findadrug/NJ-PDL.pdf.

[232] WellCare of New Jersey, New Jersey Medicaid Comprehensive Preferred Drug List, https://www.wellcare.com/~/media/PDFs/NewJersey/Shared-PDL/nj_caid_pdl_eng_07_2016.ashx.

[233] Amerigroup NJ Preferred Drug List, *supra* note 230.

coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

132. In New Mexico, Medicaid services are provided by managed care organizations. The New Mexico Human Services Department, however, is responsible for implementing a uniform formulary or preferred drug list, "taking into consideration the clinical efficacy, safety and cost effectiveness of a product."[234] Accordingly, the preferred drug list is "a list of prescription drugs for which the state will make payment without prior authorization or additional charge to the Medicaid recipient and that is based on clinical evidence for efficacy and meets the department's cost-effectiveness criteria."[235] Based on information and belief, New Mexico's managed care organizations during the relevant time period—OptumHealth New Mexico, Molina Healthcare, and Amerigroup—all included Clopidogrel or Plavix on their formulary.[236] Upon information and belief, the New Mexico plans would not have included Plavix on their Medicaid preferred

[234] N.M. STAT. ANN. § 27-2C-3(A).

[235] N.M. STAT. ANN. § 27-2-12.13(D)(8).

[236] Records are available for Molina Healthcare. *See* Molina Healthcare of New Mexico, Preferred Drug List (Formulary), http://www.molinahealthcare.com/providers/nm/medicaid/drug/PDF/formulary-2015.pdf. Records, however, are not publicly available for OptumHealth and Amerigroup because these organizations are no longer managed care organization for New Mexico. Interestingly, OptumHealth recently was accused of Medicaid fraud in several lawsuits. *See, e.g.*, Santa Fe New Mexican, OptumHealth Accused of Fraud in Three Lawsuits, http://goo.gl/z5nXZA.

drug lists, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

133. In New York, the Preferred Drug Program "promotes the use of less expensive, equally effective drugs when medically appropriate through a Preferred Drug List."[237] Clopidogrel is a preferred drug.[238] Upon information and belief, New York would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

134. In North Carolina, the Preferred Drug List Review Panel reviews the Medicaid and Health Choice Preferred Drug List recommendations of the North Carolina Department of Health and Human Services (DHHS), the Division of Medical Assistance (DMA), and the Physicians Advisory Group Pharmacy and Therapeutics Committee.[239] According to the North Carolina Medicaid and Health Choice Preferred Drug List Review Panel's Guidelines and Procedures, DHHS and DMA may change the status of a drug on the Preferred Drug List if there are

[237] N.Y. State Medicaid Fee-For-Service Pharmacy Programs, https://newyork.fhsc.com/downloads/providers/NYRx_PDP_PDL.pdf.

[238] *Id*. at 28.

[239] N.C. Medicaid & Health Choice Preferred Drug List Review Panel Guidelines and Procedures, https://www2.ncdhhs.gov/dma/pharmacy/PDL-Guidelines-07-2014.pdf.

"significant financial implications."[240] "[C]areful selection of drugs on a Preferred Drug List" is one of the ways the DMA "provides access to the right drugs at the most advantageous cost. The result is a Pharmacy Program that the [sic] best overall value to beneficiaries, providers and the state."[241] Clopidogrel is a preferred drug.[242] Upon information and belief, New Carolina would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

135. In Ohio, the Ohio Department of Medicaid ("ODM") implemented a Preferred Drug List "to ensure quality patient care while maintaining a financially responsible program."[243] "The goal of ODM drug coverage is to ensure the effective use of healthcare," which includes "minimizing overall medical costs."[244]

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[240] *Id.* "Changes to drug status [on the PDL] for financial reasons will be reviewed by the P&T committee for clinical appropriateness prior to the change in status." *Id.*

[241] N.C. Medical Assistance Health and Human Services, Outpatient Pharmacy Servs., http://dma.ncdhhs.gov/providers/programs-services/Prescription-drugs/Outpatient-Pharmacy-Services.

[242] N.C. Div. of Med. Assistance, N.C. Medicaid & Health Choice Preferred Drug List, https://ncdma.s3.amazonaws.com/s3fs-public/documents/files/PDL_2016_07_11.pdf.

[243] Ohio Department of Medicaid, Welcome to the Ohio Medicaid Pharmacy Program, http://pharmacy.medicaid.ohio.gov/.

[244] Ohio Department of Medicaid, Drug Coverage Information, http://pharmacy.medicaid.ohio.gov/drug-coverage.

Clopidogrel is a preferred drug.[245] In addition, Ohio contracts with Managed Care Plans to provide quality health care to many Ohio Medicaid customers.[246] These Managed Care Plans also maintain a preferred drug list. UnitedHealthcare—one of the Managed Care Plans—maintains a preferred drug list.[247] The UnitedHealthcare Community Plan Pharmacy and Therapeutics Committee selects drugs "to provide the most clinically appropriate and cost-effective medications for patients."[248] Clopidogrel is on the list.[249] Upon information and belief, would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

136. In Oklahoma, the Medicaid program "divides certain therapeutic categories of drugs into two or more levels called Tiers. Tier 1 medications are preferred as the first step for treating a member's health condition. They are cost effective and are usually available without [prior approval]."[250] Plavix was an

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[245] Ohio Drug Search, https://druglookup.ohgov.changehealthcare.com/DrugSearch.

[246] Ohio Department of Medicaid, Medicaid Managed Care Program, http://medicaid.ohio.gov/PROVIDERS/ManagedCare.aspx.

[247] UnitedHealthcare Community Plan, Preferred Drug List, Ohio, https://www.uhccommunityplan.com/content/dam/communityplan/plandocuments/findadrug/OH-Medicaid-PDL.pdf.

[248] *Id*.

[249] *Id*.

[250] Oklahoma HealthCare Authority, Prior Authorization (PA), https://okhca.org/providers.aspx?id=1218.

approved Tier 1 drug for recent stroke.[251] Today, Plavix is not an approved Tier 1 drug for recent stroke.[252] And, tellingly, over-the-counter aspirin is now recommended unless the patent can show a "patient-specific, clinically significant reason why" aspirin is not sufficient.[253] Upon information and belief, Oklahoma would have excluded Plavix from its Tier 1 drug list and from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

137. In Oregon, doctors and pharmacists recommend drugs for the Preferred Drug List, which is designed to identify the most effective and safe drugs.[254] "[O]nly those representing the best value to the [Oregon Health Plan] are included."[255] Clopidogrel Bisulfate is on the list.[256] Upon information and belief, Oregon would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

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[251] Oklahoma HealthCare Authority, 2010 Therapeutic Categories, https://okhca.org/providers.aspx?id=13551.

[252] Oklahoma HealthCare Authority, Cardiovascular, https://okhca.org/providers.aspx?id=12082.

[253] *Id.*

[254] The OHP Preferred List – An Overview, http://www.oregon.gov/OHA/healthplan/pages/pdl.aspx.

[255] *Id.*

[256] Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List, https://www.oregon.gov/oha/healthplan/tools/Oregon%20Medicaid%20Preferred%20Drug%20List%20-%20July%2015,%202014.pdf.

138. In Pennsylvania, the Pharmacy and Therapeutics Committee creates a preferred drug list by looking at clinical effectiveness, safety, and outcomes.[257] When all drugs are therapeutically equivalent, then the cost of the drug is considered.[258] Clopidogrel is a preferred agent.[259] Upon information and belief, Pennsylvania would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

139. In Rhode Island, the Pharmacy and Therapeutics recommends which drugs are placed on the preferred drug list.[260] According to the Rhode Island Pharmacy and Therapeutics Committee's By-Laws, "The Committee will ensure that the PDL is based on sound clinical evidence that is both safe and cost-effective."[261] Clopidogrel is on the list.[262] Upon information and belief, Rhode Island would not have included Plavix on its Medicaid preferred drug list, and

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[257] Penn. Dept. of Public Welfare, Preferred Drug List Information, http://www.dhs.pa.gov/provider/pharmacyservices/preferreddruglistinformation/.

[258] *Id*.

[259] Penn. Dept. of Human Services Preferred Drug List, http://www.providersynergies.com/services/documents/PAM_PDL.pdf.

[260] Executive Office of Health & Human Services, Pharmacy & Therapeutics Committee By-Laws, http://www.eohhs.ri.gov/Portals/0/Uploads/Documents/pandt_bylaws.pdf.

[261] *Id*.

[262] Executive Office of Health & Human Servs., R.I. Medicaid Fee for Serv., Preferred Drug List, http://www.eohhs.ri.gov/Portals/0/Uploads/Documents/pdl_list.pdf.

instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

140. In South Carolina, the Pharmacy and Therapeutics determines which drugs are placed on the preferred drug list. On information and belief, Pharmacy and Therapeutics committee considers cost-effectiveness when evaluating a drug for inclusion on the state formulary. Clopidogrel is on the list.[263] Upon information and belief, South Carolina would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

141. In South Dakota, the Pharmaceutical and Therapeutics Committee considers the "clinical efficacy, safety, and cost effectiveness of a product" when determining which drugs require prior approval.[264] The committee is specifically tasked with "addressing the high costs of prescription drugs, the increased expenditures for those prescription drugs, and the need to find ways to control the costs of prescription drugs while ensuring the needs of recipients are being met."[265]

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[263] S.C. Dept. of Health & Human Servs. Preferred Drug List, http://southcarolina.fhsc.com/Downloads/provider/SCpdl_listing_20130722.pdf.

[264] State of S.D., Office of the Gov., Executive Order 2011-23, http://sdsos.gov/general-information/assets/executive-orders/EA23_Establishment%20of%20South%20Dakota%20Medicaid%20Pharmaceutical%20and%20Therapeutics%20Commitee.pdf.

[265] *Id.*

Clopidogrel is not on the list of drugs requiring prior authorization.[266] And tellingly, just one year (from December 1, 2010 to November 30, 2011), the South Dakota Medicaid program covered $118,191.01 in Plavix prescriptions.[267] Upon information and belief, South Dakota would have included Plavix on its prior approval required list and excluded Plavix from Medicaid coverage but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

142. In Tennessee, the TennCare Pharmacy Advisory Committee considers "studies, data, and information relative to the cost effectiveness of drugs being considered for placement on the preferred drug list."[268] Clopidogrel is listed a preferred drug on the list.[269] Upon information and belief, Tennessee would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

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[266] South Dakota Medicaid, Medications Requiring Prior Authorization, http://www.hidesigns.com/assets/files/sdmedicaid/paforms/Meds_requiring_PAexternal_1114.pdf.

[267] South Dakota Department of Social Services, Medicaid P&T Committee Meeting (Mar. 2, 2012), at 115, http://www.hidesigns.com/assets/files/sdmedicaid/dur-handouts/SDPack-3-12.pdf.

[268] TennCare Pharmacy Advisory Comm., Request for Public Presentation, https://tenncare.magellanhealth.com/static/docs/Committee_Information/PAC_Requests_for_Public_Testimony.pdf.

[269] TennCare Preferred Drug List, https://tenncare.magellanhealth.com/static/docs/Preferred_Drug_List_and_Drug_Criteria/TennCare_PDL.pdf.

143. In Texas, "[p]referred drugs are medications recommended by the Texas Drug Utilization Review (DUR) Board for their efficaciousness, clinical significance, cost effectiveness, and safety for clients."[270] Clopidogrel is listed as a preferred agent on the preferred drug list.[271] Upon information and belief, Texas would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

144. In Utah, the Division of Health Care Financing ("Utah DHCF") has established a Preferred Drug List.[272] Upon the recommendation of the Utah Pharmacy and Therapeutics (which consists of physicians and pharmacists) ("P&T Committee"), the Utah DHCF "select[s] the therapeutic classes and select[s] the most clinically effective and cost effective drugs within each class" for the Preferred Drug List.[273] The P&T Committee is required to base its determinations and recommendation on clinical and cost-related factors.[274] For example, "[i]f clinical and therapeutic considerations are substantially equal, then the P&T

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[270] Texas Medicaid/CHIP Vendor Drug Program, Preferred Drugs, http://www.txvendordrug.com/formulary/preferred-drugs.shtml.

[271] Health & Human Servs. Commission, Tex. Medicaid Preferred Drug List & Prior Authorization Criteria, http://www.txvendordrug.com/formulary/downloads/2016-0721-preferred-drug-list.pdf.

[272] UTAH ADMIN. CODE r. R414-60B-1(1).

[273] *Id*. at R414-60B-4(1).

[274] *Id*. at R414-60B-7.

Committee shall recommend to DHCF that it consider only cost."[275] Clopidogrel is listed as a preferred drug.[276] Upon information and belief, Utah would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

145. In Vermont, the Drug Utilization Review Board determines which drugs are placed on its preferred drug list.[277] The DUR board is tasked with designing a preferred drug list that reduces the cost of providing prescriptions but also maintains a high quality in prescription drug therapies.[278] Clopidogrel is on Vermont's preferred drug list.[279] Upon information and belief, Vermont would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

146. In Virginia, the Pharmacy and Therapeutics Committee develops its preferred drug list by considering the safety and clinical effectiveness as well as

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[275] *Id*. at R414-60B-7(1)

[276] Preferred Drug List, https://medicaid.utah.gov/pharmacy/PDL/files/Utah%20Medicaid%20PDL%20(08-01-16).pdf.

[277] Dept. of Vt. Health Access, Drug Utilization Review Board Description & Info., http://dvha.vermont.gov/advisory-boards/drug-utilization-review-board-description-information.

[278] *Id*.

[279] Vt. Preferred Drug List & Drugs Requiring Prior Authorization, http://dvha.vermont.gov/for-providers/2013-05-14-vt-pdl-quicklist-vt-may-14-2013-final.pdf.

the cost effectiveness of a drug.[280] Clopidogrel is a preferred agent on the list.[281] Upon information and belief, Virginia would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

147. In Washington, the Pharmacy and Therapeutics Committee "reviews and evaluates the safety, efficacy, and outcomes of prescribed drugs and makes" and "makes recommendations to state agencies as to which drugs to include on the Washington PDL."[282] "When a brand-name drug has been reviewed by the P&T committee, the agency may immediately designate an available, less expensive, equally effective, generic equivalent as a preferred drug."[283] Clopidogrel is a preferred drug.[284] Upon information and belief and given the State of Washington's Cost-Imposed requirements for Medicaid reimbursement, Washington would not have included Plavix (a name brand drug) on its Medicaid preferred drug list when aspirin (a generic) is at least as effective, and instead

[280] Status Report on Development of a Medicaid Preferred Drug List Program, http://www.dmas.virginia.gov/Content_atchs/pharm/pdl-d2.ppt.

[281] Va. Medicaid Preferred Drug List With Serv. Authorization Criteria, http://www.dmas.virginia.gov/Content_atchs/pharm/pdl-20130304.pdf.

[282] WASH. ADMIN. CODE § 182-530-4100(2)-(3).

[283] *Id*. § 182-530-4100(11).

[284] Wash. Preferred Drug List – 3rd Quarter 2016, http://www.hca.wa.gov/assets/program/3rd-quarter-2016-pdl-v2.pdf.

would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

148. In West Virginia, the Pharmaceutical and Therapeutics Committee reviews each drug "on its clinical merits relative to other medications in the same therapeutic class. . . . From this analysis, the clinical staff determines an agent's superiority, equivalency, or inferiority relative to comparator drugs. After the clinical review, a financial analysis is performed. This analysis incorporates utilization data from the State as well as net drug costs from the manufacturers. With this data, the financial staff determines the fiscal impact of the PDL status (preferred or non-preferred) of each medication."[285] "Medications which have been deemed to be clinically and/or economically advantageous to other similar drugs will be preferred or have preferential status on the PDL."[286] Clopidogrel is a preferred agent on West Virginia's preferred drug list.[287] Upon information and belief, West Virginia would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

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[285] West Virginia Bureau for Medical Services, PDL FAQs, http://www.dhhr.wv.gov/bms/BMS%20Pharmacy/Pages/PDL-FAQs.aspx.

[286] *Id*.

[287] Bureau for Medical Servs., W. Va. Medicaid, Preferred Drug List with Prior Authorization Criteria, http://www.dhhr.wv.gov/bms/BMS%20Pharmacy/Documents/Preferred%20Drug%20List/2013/WV%20PDL04242013v2013_3f.pdf.

149. In Wisconsin, a Prior Authorization Advisory Committee determines whether certain drugs should be preferred or non-preferred. The Committee makes its recommendations "based primarily on objective evaluations of a drug's relative safety, effectiveness, medical necessity, clinical outcomes and relative cost to the Wisconsin Medicaid program of the agents, in comparison with other therapeutically interchangeable alternative agents in the same class of drugs."[288] Meetings before the Committee are open to the public, and the Committee allows public comments.[289] Clopidogrel is a preferred drug.[290] Upon information and belief, Wisconsin would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

150. In Wyoming, the Pharmacy and Therapeutics Committee considers the "costs of drug therapy . . . after clinical and patient considerations" when creating the Medicaid preferred drug list.[291] Clopidogrel is a preferred agent.[292]

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[288] Wisconsin Medicaid Pharmacy Prior Authorization Advisory Committee, Department Guidelines for the Wisconsin Medicaid Pharmacy Prior Authorization Advisory Committee, at 8, https://goo.gl/P8yFyO.

[289] *Id*. at 10.

[290] Wisconsin Medicaid, BadgerCare Plus Standard, and SeniorCare Preferred Drug List – Quick Reference, https://www.forwardhealth.wi.gov/WIPortal/content/provider/medicaid/pharmacy/resources.htm.spage#.

[291] Wyo. Drug Utilization Review, Mission Statement, http://www.uwyo.edu/dur/mission_statement/.

Upon information and belief, Wyoming would not have included Plavix on its Medicaid preferred drug list, and instead would have excluded Plavix from Medicaid coverage, but for the false marketing of BMS/Sanofi regarding Plavix's efficacy over aspirin.

151. BMS/Sanofi falsely marketed Plavix to physicians and pharmacists—the very same people who sit on formulary committees—in order to trick states into including Plavix on their formulary when they otherwise would not have done so, considering that aspirin is at least as effective and extraordinarily cheaper for certain indication. By misleading the states to include Plavix on their respective formulary, BMS/Sanofi fraudulently set into motion a scheme for payment of false claims for Plavix. BMS/Sanofi did not just mislead the doctors into prescribing Plavix when it was neither medically necessary nor cost effective. They also fraudulently induced the formulary committees to include Plavix on each state's formulary, which triggered an automatic Government Payor obligation to reimburse Plavix prescriptions—even when Plavix did not meet the requirements for inclusion on the formulary. Reimbursements for Plavix in this context constitute false claims under the FCA and under the State FCAs.

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[292] Wyo. Medicaid, Preferred Drug List (PDL) – September 10, 2013, http://www.wymedicaid.org/sites/default/files/ghs-files/pdl/2013-09-12/pdleffective-09-10-13.pdf.

152. Absent Defendants' false and misleading statements to physicians and pharmacists, Plavix would not have been on the formulary, and therefore, would not have been automatically reimbursed. Defendants' false and misleading statements—both to the formulary committee and to the physicians who wrote the Plavix prescriptions that were wrongfully reimbursed, were not just material to the Government Payor's payment decision. They created a fraudulent system that resulted in an inescapable duty to reimburse Plavix prescriptions—when Plavix did not in fact meet formulary requirements.

153. This blatantly fraudulent conduct is at the very core of the misconduct Congress and the various states intended to prevent under the FCA and the State FCAs. Accordingly, this also is an action to recover damages and civil penalties under the FCA and the State FCAs on behalf of the United States, all of the Participating States, and Relator Dickson for claims made from March 30, 2005 to the present for the automatic reimbursements of Plavix caused by BMS/Sanofi's fraudulently induced inclusion of Plavix on each state's formulary for indications where Plavix is no more effective, and extraordinarily more expensive, than aspirin.

E. There are No Bars to Recovery

154. None of the False Claims Act Section 3730(e) bars to recovery apply to Dickson or, in the alternative, Dickson is an original source as defined

therein.[293] Dickson has direct and independent knowledge of the information on which the allegations are based.[294] As required pursuant to 31 U.S.C. §§ 3730(b) and (e), Dickson has voluntarily provided information, oral and/or written, and has sent disclosure statement(s) of all material evidence, information, and documents related to this complaint, both before and contemporaneously with filing, to the Attorney General of the United States and the United States Attorney for the Southern District of Illinois. In addition, Dickson voluntarily provided copies of the Original Complaint in this case with all exhibits to the Participating States prior to the unsealing of the Original Complaint. Further, the "related action" bar does not apply to Dickson.[295]

155. As a member of BMS/Sanofi's sales force for almost a decade, Relator witnessed firsthand an ongoing scheme to promote Plavix as more effective than aspirin. In so doing, BMS/Sanofi defrauded the formulary committees into including Plavix on each state's formulary and defrauded physicians into prescribing Plavix even though the drug was no more effective than a cheaper and safer aspirin.[296] BMS/Sanofi fueled this scheme by training and instructing their sales representatives, including Relator, to confuse physicians and to "focus sales calls on physicians and prescribers whose patients relied on"

[293] *See* 31 U.S.C. § 3730(e)(4)(B).
[294] *See* Ex. A (Affidavit).
[295] *See* 31 U.S.C. § 3730(b)(5).
[296] *See* Ex. A (Affidavit) ¶¶ 18-19, 22, 29, 33, 36, 37.

Medicaid and Medicare—doctors with "an inherent willingness to prescribe more expensive drugs."[297] This information was not publicly disclosed prior to this lawsuit.

156. Additionally, Relator has direct and independent knowledge of the information on which the allegations are based because of her position with BMS/Sanofi, where she was trained as a sales representative to mislead doctors and pharmacists about Plavix.[298] The scheme involved BMS/Sanofi mischaracterizing clinical studies and instructing their sales force to confuse physicians and pharmacists by promoting a false narrative regarding Plavix's efficacy.[299] Relator's direct and independent knowledge of the deceptiveness of BMS/Sanofi's marketing strategy results from the discrepancies between her sales training about Plavix and her instructions on its promotion.[300] For example, she received the CAPRIE Road Map for training purposes, which revealed Plavix's non-significant efficacy data, and yet was instructed by BMS/Sanofi to promote Plavix in direct contradiction to its results.[301]

157. To the extent, if any, that this case is deemed to be a related action and that facts set forth herein are deemed to be the same as facts underlying an

[297] *Id.* ¶ 33.
[298] *See id.* ¶¶ 18-19, 22, 29, 32, 33, 36, 37.
[299] *Id.*
[300] *Id.*
[301] *Id.* ¶¶ 15-16, 18.

existing qui tam False Claims Act action pending at the time of filing of this action, as prohibited in 31 U.S.C. § 3730 (e)(3), said factual allegations in common with either pending action, which would cause this to be a related cause of action, are hereby expressly excluded from this action, but only to the limited extent necessary to exclude such preemption.

158. Furthermore, to the extent that the court finds that the allegations or transactions set forth herein are based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the United States is already a party, if any such proceedings exist, then the allegations or transactions referred to herein that the court deems are based upon allegations or transactions which are the subject of any such civil suit or administrative civil, money penalty proceeding are expressly excluded, but only for the specific time periods, specific companies, and specific allegations or transactions as necessary.

159. Moreover, in its August 20, 2015 Opinion, this Court recognized that Dickson is an original source and, as such, the FCA's public disclosure bar, 31 U.S.C. § 3730(e)(4), does not apply to prohibit allegations of BMS/Sanofi's conduct under either the pre-2010 statute or the post-2010 statute.

F. State False Claim Acts

160. Each of the Participating States have state statutes analogous to the FCA ("State FCAs"). A majority of the Participating States are Cost-Imposed Participating States. The Cost-Imposed Participating States are: Colorado, Connecticut, Delaware, Florida, Georgia, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, North Carolina, Oklahoma, Rhode Island, and Tennessee. This is an action to recover the portion of Plavix reimbursements paid for by states with State FCAs and civil penalties on behalf of the Cost-Imposed Participating States and Relator Dickson arising from false or fraudulent statements, claims, and acts by Defendants made in violation of the State FCAs.

161. As detailed in Dickson's testimony, BMS/Sanofi promoted Plavix as a superior drug to aspirin for certain indicated uses and charged approximately 100 times more for Plavix than could be charged for aspirin when in fact Plavix was no more effective than aspirin for certain indicated usages. BMS/Sanofi focused its marketing efforts on doctors whose patient populations were composed of Government Payor subscribers. BMS/Sanofi's conduct caused physicians to submit many prescriptions for Plavix that resulted in grossly inflated costs for Government Payors with no additional benefit to the covered patient, when compared to aspirin.

162. The State FCAs provide that persons who knowingly present, or cause to be presented, false or fraudulent claims for payment to an officer of the State, including false or fraudulent claims for payment or approval under medical assistance programs, are liable for civil penalties and damages that the State sustains because of the act of that person. In addition, a person violating these State statutes can be liable for the costs of a civil action brought to recover such penalties and damages.

163. The State FCAs allow persons having knowledge of a false or fraudulent claim against the State to bring an action for themselves and the State and to share in any recovery. Based on these provisions, Dickson, on behalf of each of the Cost-Imposed Participating States, seeks through this action to recover damages and civil penalties arising from BMS/Sanofi's false and/or fraudulent conduct in connection with its false statements regarding the efficacy and cost effectiveness of Plavix. Dickson believes that the Cost-Imposed Participating States have suffered significant damages as a result of BMS/Sanofi's false and/or fraudulent conduct.

164. In addition, each of the Participating States requires drugs to be cost-effective in order to be placed on the respective state formulary. As detailed above, BMS/Sanofi fraudulently induced state review boards in all of the Participating States to place Plavix on their respective state's formulary for

indications for which Plavix was no more effective than aspirin and extraordinarily more expensive. BMS/Sanofi's fraud resulted in the obligation of each of the Participating States to reimbursement of Plavix each time it was prescribed for formulary indications—even though Plavix did not meet the cost-effectiveness requirements for inclusion on each of the Participating States' formulary. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before each Participating State's respective formulary committee caused the payment of false claims in violation of each Participating State's State FCA.

165. Based on the State FCAs, Dickson, on behalf of each of the Participating States, seeks through this action to recover damages and civil penalties arising from BMS/Sanofi's false and/or fraudulent conduct in connection with its false statements regarding the efficacy and cost effectiveness of Plavix before each Participating State's formulary committee. Dickson believes that the Cost-Imposed Participating States have suffered significant damages as a result of BMS/Sanofi's false and/or fraudulent conduct.

V.
FACTUAL ALLEGATIONS

166. BMS/Sanofi have acted in a comprehensive scheme to defraud federal and state governments while illegally and deceptively promoting Plavix to further increase Plavix sales. BMS/Sanofi's scheme involved false statements

misrepresenting Plavix's efficacy and cost effectiveness compared to cheaper alternatives such as aspirin.

B. BMS/Sanofi Manipulated Clinical Trial Data to Support Fraudulent Claims Regarding Plavix's Efficacy Compared to Cheaper Alternatives Such as Aspirin

167. BMS/Sanofi improperly lumped together different patient trial groups to support a claim of superiority over aspirin, an exponentially cheaper alternative.[302] For example, Plavix is indicated for treatment of patients who have recently suffered from stroke.[303] Plavix's indication for patients with recent strokes was obtained based on the *Clopidogrel [Plavix] vs. Aspirin in Patients at Risk for Ischemic Events* ("CAPRIE") clinical trial.[304] The CAPRIE trial enrolled 19,185 patients with approximately 6,300 patients in each of three different subgroups.[305] The three subgroups included (a) patients who experienced a recent stroke, (b) patients who experienced recent myocardial infarction ("MI"), and (c) patients who experienced symptomatic peripheral arterial disease ("PAD").[306] In

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[302] *See id.*

[303] Ex. B (Plavix Insert) at 2.

[304] *See* CAPRIE Trial Abstract, attached hereto as Exhibit F ("Ex. F (CAPRIE)"); s*ee also* CAPRIE Steering Committee, *A randomised, blinded, trial of clopidogrel versus aspirin in patients at risk of ischaemic events (CAPRIE)*, THE LANCET, Vol. 348, Issue 9038 (Nov. 16, 1996).

[305] *See* Ex. F (CAPRIE); s*ee also* CAPRIE Steering Committee, *supra* note 304.

[306] *See* Ex. F (CAPRIE); s*ee also* CAPRIE Steering Committee, *supra* note 304.

each subgroup, half of the patients were given 325 mg of aspirin once daily and the other half were given 75 mg of Plavix daily. [307]

168. The primary efficacy endpoint for the trial was the combination of ischemic stroke, MI, or vascular death.[308] Put another way, in each of the three subgroups the trial compared the combined rates of ischemic stroke, myocardial infarction, and vascular death between patients receiving Plavix against those receiving aspirin to determine whether Plavix was more or less effective in preventing those events, i.e. ischemic stroke, MI, and vascular death.[309] In the CAPRIE trial, Plavix demonstrated a marginally significant 8.7% relative risk reduction of the primary endpoint compared to aspirin.[310] The absolute risk reduction was 0.5%, meaning that for every 1,000 patients treated with Plavix only five patients benefited from Plavix treatment as compared to aspirin treatment.[311]

169. The CAPRIE composite data was driven primarily by the PAD subgroup, which showed a relative risk reduction of 23.8% in the primary endpoint.[312] However, in the recent stroke and recent myocardial infarction

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[307] *See* Ex. F (CAPRIE); s*ee also* CAPRIE Steering Committee, *supra* note 304; Ex. A (Affidavit) ¶¶ 10-11.

[308] *See* Ex. F (CAPRIE); s*ee also* CAPRIE Steering Committee, *supra* note 304; Ex. A (Affidavit) ¶ 11.

[309] Ex. A (Affidavit) ¶ 12.

[310] Ex. F (CAPRIE); s*ee also* CAPRIE Steering Committee, *supra* note 304; Ex. A (Affidavit) ¶ 12.

[311] Ex. A (Affidavit) ¶ 12.

[312] *Id.* ¶ 13.

subgroups, CAPRIE demonstrated that there was no statistically significant reduction in the primary endpoint for patients taking Plavix as compared to patients taking aspirin.[313] Indeed, in the case of aspirin, even though no statistically significant reduction existed favoring aspirin over Plavix for recent myocardial infarctions, the study concluded that the trend favored aspirin over Plavix.[314] This subgroup information was included in the CAPRIE Road Map.[315] The CAPRIE Road Map was created by Sanofi and used only for internal sales training.[316] It was not to be used in sales presentations to doctors.[317] On pamphlets provided to physicians summarizing the CAPRIE study, the subgroup analysis was not provided.[318] Only the overall 8.7% reduction in the primary endpoint was provided.[319] The subgroup analysis would have demonstrated that in two of the three subgroups (recent stroke and recent myocardial infarction patients) Plavix failed to reduce instances of ischemic stroke, MI, or vascular death any more than simple treatment with aspirin.[320]

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[313] *Id.* ¶ 14; *see* CAPRIE Road Map, attached hereto as Exhibit G ("Ex. G (CAPRIE Road Map)").

[314] Ex. G ("Ex. G (CAPRIE Road Map)").

[315] Ex. A (Affidavit) ¶ 15; Ex. G (CAPRIE Road Map).

[316] Ex. A (Affidavit) ¶ 15; Ex. G (CAPRIE Road Map) at 1 (stating "For Sales Training Only; Not to be Used in Selling Presentations").

[317] Ex. A (Affidavit) ¶ 15; Ex. G (CAPRIE Road Map) at 1 (stating "For Sales Training Only; Not to be Used in Selling Presentations").

[318] Ex. A (Affidavit) ¶ 15; *see, e.g.*, Ex. D (Efficacy and Safety of PLAVIX).

[319] Ex. A (Affidavit) ¶ 15; *see* Ex. D (Efficacy and Safety of PLAVIX) at 4.

[320] Ex. A (Affidavit) ¶ 15; Ex. G (CAPRIE Road Map).

170. Despite the non-significant efficacy data in the CAPRIE trial for stroke patients, company sales pamphlets (citing CAPRIE) claimed that there was "proven efficacy" of Plavix over aspirin in ischemic stroke patients.[321] This claim was rebutted when in 2010 the American Stroke Association's ("ASA") *Guidelines for the Prevention of Stroke in Patients with Ischemic Stroke or Transient Ischemic Attack* were amended to state that, "[n]o studies have compared clopidogrel with placebo, and studies comparing it with other antiplatelet agents have not clearly established that it is superior or even equivalent to any one of them."[322]

171. The 2010 ASA guidelines recommend the use of Plavix for the treatment of stroke patients only if the patients are allergic to aspirin.[323] The 2010 ASA guidelines provide a Class I, Level of Evidence A recommendation for the use of Aspirin in the secondary prevention of stroke.[324] The guidelines only provide a Class IIA, Level of Evidence B recommendation for the use of Plavix in the secondary prevention of stroke.[325] Class I means that a treatment should be

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[321] Ex. A (Affidavit) ¶ 16; *see* Ex. D (Efficacy and Safety of PLAVIX) at 4.

[322] Karen L. Furie *et al*., *Guidelines for the Prevention of Stroke in Patients with Ischemic Stroke or Transient Ischemic Attack* at 248, attached hereto as Exhibit H ("Ex. H (ASA Guidelines)") and available at http://stroke.ahajournals.org/cgi/content/full/42/1/227; *see also* Ex. A (Affidavit) ¶ 16.

[323] Ex. H (ASA Guidelines) at 249.

[324] Ex. A (Affidavit) ¶ 17.

[325] *Id.*

administered.[326] Class IIA means that additional studies with focused objectives are needed but that it is reasonable to administer treatment.[327] Regardless, BMS/Sanofi ordered its sales personnel to promote Plavix as being superior to aspirin in stroke patients.[328] As a result, Plavix was regularly and systematically promoted as superior to aspirin for treatment of stroke patients.[329]

172. BMS/Sanofi also encouraged physicians to switch patients from aspirin to Plavix if they suffered a stroke while taking aspirin.[330] According to ASA, however, "there have been no clinical trials to indicate that switching anti-platelet agents reduces the risk for subsequent events."[331]

173. BMS/Sanofi also misled physicians regarding the efficacy of Plavix plus aspirin dual therapy following coronary artery bypass grafting ("CABG"). Upon information and belief, BMS/Sanofi obtained a label change for Plavix based on The Clopidogrel in Unstable angina to prevent Recurrent ischemic Events ("CURE") Trial[332] to indicate that Plavix was effective for treatment post-CABG.

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[326] *Id.*
[327] *Id.*
[328] *Id.*¶ 18.
[329] *Id.*
[330] *Id.*¶ 19.
[331] Ex. H (ASA Guidelines) at 248; *see also* Ex. A (Affidavit) ¶ 20.
[332] *See* Circulation – Journal of the American Heart Association, *Benefits and Risks of the Combination of Clopidogrel and Aspirin in Patients Undergoing Surgical Revascularization for Non-ST-Elevation Acute Coronary Syndrome: The Clopidogrel in Unstable angina to prevent Recurrent ischemic Events (CURE) Trial* (Aug. 16, 2004), attached hereto as Exhibit J ("Ex. J (CURE Trial)").

However, a subgroup analysis of the CURE study revealed that "the benefit of [Plavix plus aspirin] therapy was entirely preoperative, while patients were awaiting surgery. No benefit was seen for clopidogrel use after CABG in the CURE trial."[333] This analysis was confirmed by The Clopidogrel After Surgery for Coronary Artery Disease ("CASCADE") Trial, which found that "[c]ompared with aspirin monotherapy, the combination of aspirin plus clopidogrel did not significantly reduce the process of SVG intimal hyperplasia 1 year after coronary artery bypass grafting."[334] Despite its lack of efficacy for post-CABG patients, upon information and belief Plavix plus aspirin dual therapy is prescribed for approximately 20-30% of the approximately 500,000 CABG procedures performed each year in the United States.

C. BMS/Sanofi Fraudulently Downplayed and Misrepresented Specific and Known Health Risks of Plavix Use Compared to Cheaper Alternatives Such as Aspirin

174. The CAPRIE trial also showed that there was less gastrointestinal bleeding in patients taking Plavix compared to aspirin.[335] However, the aspirin

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[333] *See* Kulik, Alexander, *et al.*, *Clopidogrel After Coronary Artery Bypass Graft Surgery*, J. AM. C. CARDIOLOGY (Jan. 4, 2012) attached hereto as Exhibit K ("Ex. K. (Clopidogrel After Coronary)").

[334] *See* Circulation – Journal of the American Heart Association, *Aspirin Plus Clopidogrel Versus Aspirin Alone After Coronary Artery Bypass Grafting: The Clopidogrel After Surgery for Coronary Artery Disease (CASCADE) Trial* (Dec. 6, 2010), attached hereto as Exhibit L ("Ex. L (CASCADE Trial)").

[335] Ex. F (CAPRIE); *see also* Ex. A (Affidavit) ¶ 21.

dose used in CAPRIE was 325 mg per day for all patients.[336] Presently, physicians recommend an aspirin dose of as little as 50 mg per day, which is equally effective but minimizes the bleeding risk.[337] BMS/Sanofi ordered its sales force to promote Plavix as comparably safe to aspirin based on the CAPRIE study even though the CAPRIE study compared Plavix to a more toxic dose of aspirin that is not regularly prescribed today.[338]

175. CAPRIE was published in 1996.[339] Following this study, BMS/Sanofi have not further tested Plavix against aspirin to determine whether a more commonly prescribed (*i.e.*, lower) dose of aspirin supports BMS/Sanofi's claims that Plavix imposes a lower risk of gastrointestinal bleeding when compared to aspirin (as its used in a therapeutic context).[340] However, in a study published in the January 20, 2005 New England Journal of Medicine (the "Chan Study"), Plavix was shown to cause significantly more gastrointestinal bleeding than aspirin plus esomeprazole (brand name Prilosec) in patients with a history of aspirin-induced ulcers.[341] The Chan Study showed that switching patients to Plavix if they have

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[336] Ex. F (CAPRIE); *see also* Ex. A (Affidavit) ¶ 21.

[337] *See, e.g.*, Ex. A (Affidavit) ¶ 21.

[338] *Id.* ¶¶ 21-22.

[339] *See* CAPRIE Steering Committee, *supra* note 304 (published Nov. 16, 1996).

[340] Ex. A (Affidavit) ¶ 23.

[341] Francis Chan, *Clopidogrel versus Aspirin and Esomeprazole to Prevent Recurrent Ulcer Bleeding*, 352 N. ENGL. J. MED. 3, at 241-243 (2005), attached hereto as Exhibit I ("Ex. I (Chan Study)").

ulcers with aspirin is not safe and that it would be cheaper to simply add esomeprazole (an inexpensive over-the-counter medication) to aspirin.[342] The results of the Chan Study were not disclosed to prescribing neurologists.

176. More recently, on November 19, 2011, the National Institutes of Health ("NIH") and the National Institute of Neurological Disorders and Stroke ("NINDS") prematurely stopped a study regarding the efficacy of Plavix plus aspirin in preventing a recurrent stroke on the recommendation of its Data and Safety Monitoring Board, which found that 6.5% of patients taking Plavix plus aspirin experienced a bleeding event versus just 3.3% taking aspirin alone.[343] Additionally, 5.8% of patients taking Plavix plus aspirin died (from any cause) versus 4.1% taking aspirin alone.[344] The NINDS concluded that there was "little likelihood of benefit in favor of aspirin plus clopidogrel (Plavix) on recurrent stroke should the study continue to conclusion."[345] And the NINDS noted that "[t]hese results support current guidelines that recommend against the use of the combination of clopidogrel plus aspirin for secondary stroke prevention."[346]

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[342] *See* Ex. I (Chan Study); Ex. A (Affidavit) ¶ 24.

[343] *See* U.S. National Library of Medicine, National Institutes of Health, Clinical Advisory: Secondary Prevention of Small Subcorticol Strokes Trial (Nov. 17, 2011), attached hereto as Exhibit M ("Ex. M (NIH Press Release)").

[344] *Id.*

[345] *Id.*

[346] *Id.*

177. The Short- Versus Long-term Duration of Dual Antiplatelet Therapy After Coronary Stenting: A Randomized Multicentre Trial (the "Duration Trial") studied the difference in efficacy of continuing Plavix plus aspirin dual therapy for 6 months after coronary stenting versus continuing dual therapy for 24 months after coronary stenting.[347] While the Duration Trial's primary conclusion was that continuing Plavix with aspirin for 24 months post-coronary stenting "was not significantly more effective than a 6-month clopidogrel regimen in reducing the composite of death for any cause, myocardial infarction or cerebrovascular accident,"[348] the Duration Trial did observe the significant increase in bleeding caused by increased exposure to Plavix. Specifically, "2-year clopidogrel therapy resulted in a significant increase of actionable bleeding episodes, which included events requiring medical or surgical treatment, red blood cell transfusion and life threatening events."[349]

[347] *See* American Heart Association, Short- Versus Long-Term Duration of Dual Antiplatelet Therapy After Coronary Stenting: A Randomized Multicentre Trial, Circulation (Mar. 21, 2012), attached hereto as Exhibit N ("Ex. N (Duration Trial)"), at 2.

[348] *Id*. at 2, 13, 17.

[349] *Id*. at 13 (citations omitted).

D. BMS/Sanofi Mischaracterized Clinical Studies that Contradicted the Sales Campaign

178. Aggrenox (aspirin + dipyridamole) is also recommended over Plavix for stroke patients in the 2010 ASA Guidelines.[350] The efficacy and safety of Aggrenox versus aspirin is supported by three large clinical trials, whereas only one clinical trial (CAPRIE) compares Plavix with aspirin.[351] The *Prevention Regimen for Effectively Avoiding Second Strokes* ("PRoFESS") trial compared Aggrenox with Plavix in the prevention of secondary stroke in patients who have experienced a recent stroke.[352]

179. According to the ASA, the PRoFESS trial "showed no difference in stroke recurrence among patients assigned to [Plavix] compared with patients assigned to [Aggrenox]."[353] There was also no statistically significant difference between the two drugs in causing major hemorrhagic events.[354] However, BMS/Sanofi presented the PRoFESS data in a manner designed to confuse physicians and enforce an unsupported believe that Aggrenox was inferior to Plavix.[355]

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[350] Ex. A (Affidavit) ¶ 25.
[351] *Id.* ¶ 26.
[352] Ex. E (PRoFESS Summary).
[353] Ex. H (ASA Guidelines) at 247.
[354] *Id.*
[355] Ex. A (Affidavit) ¶ 29.

180. Rather than state that PRoFESS showed no difference between the two drugs, BMS/Sanofi compelled its sales force to emphasize that "Aggrenox failed to meet the primary end point of noninferiority for recurrent stroke relative to Plavix."[356] BMS/Sanofi further claimed that "it should not be concluded from the study that Aggrenox has similar efficacy and safety to Plavix in stroke patients."[357] Despite the inconclusiveness of the PRoFESS data, the ASA still recommends Aggrenox over Plavix due to substantially more clinical data favoring its use in stroke patients.[358] The purpose of talking to physicians about the PRoFESS trial was to increase Plavix's market share in the post-stroke population.[359]

E. BMS/Sanofi Targeted Doctors whose Patients Rely on Government Payors for Health Care Treatment so as to Wrongfully Inflate Sales and Profits at a Tremendous Cost to American Taxpayers

181. BMS/Sanofi focused sales calls on physicians who prescribed medication for large populations of patients covered by Government Payors.[360] The purpose of targeting such patients was based on physicians' inherent willingness to prescribe more expensive drugs to patients who relied on

[356] *Id.*; Ex. E (PRoFESS Summary) at 2.
[357] Ex. A (Affidavit) ¶ 29; Ex. E (PRoFESS Summary) at 5.
[358] *See* Ex. H (ASA Guidelines); Ex. A (Affidavit) ¶ 30.
[359] Ex. A (Affidavit) ¶ 31.
[360] *Id.* ¶¶ 32-38.

government assistance in obtaining prescription medication.[361] Accordingly, Plavix provided a unique two-fold opportunity for BMS/Sanofi to capitalize on Government Payors by illegally raiding government coffers.[362]

182. First, during the relevant period, Plavix enjoyed continued patent protection, meaning no generic prescription equivalent was available.[363] Therefore, if a doctor wished to prescribe clopidogrel, Plavix was her only option.[364] Second, by making fraudulent claims regarding Plavix's efficacy against aspirin, BMS/Sanofi convinced many physicians of Plavix's false superiority to aspirin and its unique qualities.[365] This scheme left many physicians with the false impression that Plavix was essentially the only option for effective patient care in a host of contexts.[366]

183. As explained above in the Cost-Imposed States, cost effectiveness is a condition of government payment for prescription drugs under each state's Medicaid program. BMS/Sanofi's misrepresentations about the efficacy of Plavix

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[361] *Id.* ¶ 33.
[362] *Id.* ¶ 34.
[363] *See* Ex. A (Affidavit) ¶ 35. More specifically, the FDA extended the patent protection of clopidogrel by six months, from November 17, 2011 to May 17, 2012. The FDA approved generic versions of Plavix on May 17, 2012. See FDA New Release, FDA Approved Generic Versions of Blood Thinner Plavix, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm304489.htm.
[364] Ex. A (Affidavit) ¶ 35.
[365] *Id.* ¶ 36.
[366] *Id.* ¶ 37.

when compared to aspirin deprived physicians of the opportunity to determine whether Plavix's 100 times greater cost was justified considering its lack of superior efficacy to aspirin. This deprivation resulted in numerous physicians prescribing Plavix when Plavix was not cost effective (and medically necessary) in the Cost-Imposed States. BMS/Sanofi's misrepresentations thus caused physicians to write prescriptions for Plavix in the Cost-Imposed States, which resulted in government payment when Plavix was neither medically necessary nor cost effective.

184. Specifically, when a physician writes a prescription for a Medicaid subscriber, that prescription is that physician's implied certification that the prescribed drug meets the requirements of Medicaid coverage. In addition, when a claim is submitted for payment under Medicaid, the submission also is an implied certification that the claim complies with the Medicaid coverage requirements. Importantly, as explained above, a physician's implied certification that Plavix meets Medicaid program requirements (including, in the Cost-Imposed States, that the services are cost effective) is a critical prerequisite to Medicaid reimbursement. Absent the prescribing physician's implied certification that Plavix meets program requirements, there can be no reimbursement for Plavix. Therefore, BMS/Sanofi's scheme caused physicians and pharmacists to submit claims for reimbursement that constituted false claims for government payment in the Cost-Imposed States

because Plavix was not cost effective (and not medically necessary), even though cost effectiveness is a prerequisite for government payment.

185. In addition, BMS/Sanofi fraudulently induced state review boards to place Plavix on their respective state's formulary for indications for which Plavix was neither medically necessary nor cost effective. BMS/Sanofi knowingly caused the various Government Payors to become obligated to pay for Plavix when Plavix was prescribed for formulary indications, even though Plavix had no therapeutic advantage over aspirin for these indications as was 100 times more expensive. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims.

186. Together, BMS/Sanofi's concerted efforts created a perfect storm to generate astronomical sales and profits fraudulently created by bilking federal and state governments.[367]

187. The United States, the Participating States, and Relator Dickson now seek civil damages and penalties for the monies that were paid for false Medicaid claims.

[367] *Id.* ¶ 38.

VI.
CAUSES OF ACTION

A. First Cause of Action: Federal False Claims Act Violations (31 U.S.C. § 3729-3733)

188. Dickson re-alleges and incorporates by reference each of the preceding paragraphs as if set forth fully herein.

189. This Count is brought by Relator in the name of the United States against the Defendants under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendants' violation of 31 U.S.C. § 3729(a)(1) and (a)(2). In violation of 31 U.S.C. § 3729(a)(1) and (a)(2), Defendants made and caused to be made, the false claims that have been set forth in the Complaint herein.

190. Plaintiff United States, unaware of the falsity of the claims and/or statements which Defendants caused doctors, pharmacists, and other health care providers to make to the United States, and in reliance on the accuracy thereof, paid those doctors, pharmacies, and other health care providers for claims that would otherwise not have been allowed under the Cost-Imposed States' Medicaid Programs.

191. The amounts of the false or fraudulent claims to the United States were material.

192. Plaintiff United States, being unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy thereof,

paid and may continue to pay Defendants for health care services that otherwise should not have been paid under Medicaid.

193. The United States and the state Medicaid programs have been damaged by the payment of false or fraudulent claims.

194. BMS/Sanofi knowingly presented physicians with false information regarding the efficacy of Plavix compared to cheaper alternatives such as aspirin. BMS/Sanofi manipulated, misrepresented, and/or withheld clinical data from physicians in order to convince physicians to prescribe Plavix even though Plavix was not cost effective.

195. BMS/Sanofi's actions knowingly caused physicians and pharmacists to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met requirements for Medicaid coverage. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Cost-Imposed States when Plavix did not in fact meet requirements for Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Government Payors in Cost-Imposed States. BMS/Sanofi's actions were in violation of the False Claims Act, 31 U.S.C. ¶¶ 3729-3733.

196. The United States made payment on these false or fraudulent claims. Had the United States known that BMS/Sanofi were knowingly causing physicians and pharmacists to submit such false claims for payment, the United States would not have provided reimbursement for such prescriptions under Government Payors' programs. Plavix is a prescription drug; it cannot be reimbursed without a prescription. Writing a prescription for Plavix is not some ministerial task; it is a determinative condition precedent to reimbursement. Defendants' false marketing caused physicians to conclude (wrongfully) that Plavix was medically necessary and cost effective. Had the prescribing physicians known the truth about Plavix, they would not have prescribed it, and false claims for Plavix would not have been made. These prescriptions—which were false certifications that Plavix met program requirements regarding medical necessity and cost-effectiveness—caused the Government Payors to reimburse the cost of Plavix prescriptions when such reimbursements were prohibited by the various Medicaid regimes. The false implied certification, therefore, was more than just material to the Government Payor's payment decision; it was outcome determinative. Without a prescription for Plavix—which was caused by BMS/Sanofi's fraudulent and misleading conduct—Government Payors would not have been saddled with needless and expensive false claims.

197. In addition, BMS/Sanofi fraudulently induced state review boards to place Plavix on their respective formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused the states to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the False Claims Act, 31 U.S.C. ¶¶ 3729-3733. The United States made payment on these false or fraudulent claims. For formulary drugs, a doctor's prescription is all the more important and powerful because the false implied certification (i.e., the prescription) results in Government Payor reimbursement despite the failure of certain Plavix prescriptions to satisfy the requirements for Medicaid coverage.

198. As a result, the United States has suffered and continues to suffer substantial damage.

B. Second Cause of Action: Federal False Claims Act Violations for Conspiracy (31 U.S.C. § 3729(a))

199. Dickson re-alleges and incorporates by reference each of the preceding paragraphs as if set forth fully herein.

200. Defendants BMS/Sanofi have conspired to defraud the Government by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval.

201. Defendants BMS/Sanofi conspired to fraudulently market to physicians regarding Plavix's claimed superiority to aspirin in order to defraud the government. Specifically, a prescription written for Plavix was a certification that the Plavix met requirements for Medicaid coverage. BMS/Sanofi, however, conspired to make misrepresentations to physicians about Plavix's efficacy in order to cause physicians to prescribe Plavix when Plavix did not in fact meet requirements for Medicaid coverage in the Cost-Imposed States because a cheaper alternative existed that was at least just as effective.

202. In addition, BMS/Sanofi have conspired to fraudulently induce state review boards to place Plavix on their respective state's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. BMS/Sanofi also have conspired to cause the United States to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's conspiracy to defraud the government caused the payment of claims violation of the False Claims Act, 31 U.S.C. ¶¶ 3729-3733.

203. Defendants BMS/Sanofi have conspired to defraud the Government by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim.

204. Defendants BMS/Sanofi have conspired to defraud the Government by knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government.

205. As a result, the United States has suffered and continues to suffer substantial damage.

C. Third Cause of Action: California State Law Claims for Violations of the California False Claims Act (CAL. GOV. CODE §§ 12650-12655)

206. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

207. This is a claim against BMS/Sanofi for treble damages and penalties on behalf of the State of California under the California False Claims Act, California Government Code §§ 12650-12655.

208. If the State of California had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the Plavix prescription.

209. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the California government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of California.

210. By virtue of the above-described unlawful acts, BMS/Sanofi knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims under the Medicaid program.

211. BMS/Sanofi fraudulently induced California's state review board to place Plavix on California's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused California to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the California Government Code §§ 12650-12655.

212. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or

presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

213. By reason of Defendants' conspiracy and unlawful acts, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

214. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

D. Fourth Cause of Action: Colorado State Law Claims for Violations of the Colorado Medicaid False Claims Act (C.R.S. § 25.5-4-304 *et seq*.)

215. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

216. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act C.R.S. § 25.5-4-304 et seq.

217. The Colorado Medicaid False Claims Act C.R.S. § 25.5-4-304 et seq. provides for liability for inter alia any person who engages in any or all of the following conduct:

> (a) Knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> (c) Has possession, custody, or control of property or money used, or to be used, by the state in connection with the "Colorado Medical Assistance

> Act" and knowingly delivers, or causes to be delivered, less than all of the money or property;
>
> (d) Authorizes the making or delivery of a document certifying receipt of property used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> . . .
>
> (f) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act", or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act";
>
> (g) Conspires to commit a violation of paragraphs (a) to (f) of this subsection (1).

218. By virtue of the conduct alleged herein, Defendants knowingly violated the Colorado Medicaid False Claims Act.

219. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Colorado to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Colorado. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Colorado when Plavix did not in fact meet requirements for Colorado's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly

caused the submission of false claims for payment by Colorado in violation of the Colorado Medicaid False Claims Act, C.R.S. § 25.5-4-304 *et seq*.

220. In addition, BMS/Sanofi fraudulently induced Colorado's state review board to place Plavix on Colorado's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Colorado to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the Colorado Medicaid False Claims Act C.R.S. § 25.5-4-304 et seq.

221. The Colorado Medicaid Program, unaware of the falsity or fraudulent nature of Defendants' illegal conduct, paid for claims that otherwise would not have been allowed.

222. If the State of Colorado had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

223. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Colorado government while illegally and

deceptively promoting Plavix to further increase Plavix sales within the State of Colorado.

224. By reason of these improper payments, the Colorado Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

E. Fifth Cause of Action: Connecticut State Law Claims for Violations of the Connecticut False Claims Act (CONN. GEN. STAT. ANN. § 17b-301a *et seq.*)

225. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

226. This is a claim for treble damages and penalties under the Connecticut False Claims Act, CONN. GEN. STAT. ANN. § 17b-301a et seq.

227. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, to an officer or employee of the State of Connecticut, false or fraudulent claims for payment or approval under medical assistance programs administered by the Department of Social Services.

228. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to secure the payment or approval by the State of Connecticut of false or fraudulent claims under medical assistance programs administered by the Department of Social Services.

229. By virtue of the acts described above, Defendants conspired with each other and with others to defraud the State of Connecticut by securing the allowance or payment of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services.

230. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Connecticut to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Connecticut. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Connecticut when Plavix did not in fact meet requirements for Connecticut's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Connecticut in violation of the Connecticut False Claims Act, CONN. GEN. STAT. ANN. § 17b-301a et seq.

231. In addition, BMS/Sanofi fraudulently induced Connecticut's state review board to place Plavix on Connecticut's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Connecticut to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these

indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the Connecticut False Claims Act, CONN. GEN. STAT. ANN. § 17b-301a et seq.

232. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

233. By reason of the Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

234. If the State of Connecticut had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

235. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Connecticut government while illegally and deceptively promoting Plavix to further increase Plavix sales within the State of Connecticut.

236. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

F. Sixth Cause of Action: Delaware State Law Claims for Violations of the Delaware False Claims and Reporting Act (6 DEL. CODE ANN. § 1201(a)(1) and (2))

237. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

238. This is a claim for treble damages and penalties against BMS/Sanofi on behalf of the State of Delaware under the Delaware False Claims and Reporting Act, 6 DEL. CODE ANN. §1201(a)(1) and (2).

239. If the State of Delaware had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

240. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Delaware government while illegally and deceptively promoting Plavix to further increase Plavix sales within the State of Delaware.

241. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted

material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

242. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Delaware to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Delaware. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Delaware when Plavix did not in fact meet requirements for Delaware's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Delaware in violation of the Delaware False Claims and Reporting Act, 6 DEL. CODE ANN. §1201(a)(1) and (2).

243. In addition, BMS/Sanofi fraudulently induced Delaware's state review board to place Plavix on Delaware's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Delaware to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of

the Delaware False Claims and Reporting Act, 6 DEL. CODE ANN. §1201(a)(1) and (2).

244. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

245. By reason of Defendants' conspiracy and unlawful acts, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

246. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

G. Seventh Cause of Action: Florida State Law Claims for Violations of the Florida False Claims Act (FL. STAT. §§ 68.081-68.090)

247. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

248. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Florida under the Florida False Claims Act, FL. STAT. § 68.081-68.090.

249. If the State of Florida had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

250. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Florida government while illegally and deceptively promoting Plavix to further increase Plavix sales within the State of Florida.

251. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

252. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Florida to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Florida. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Florida when Plavix did not in fact meet requirements for Florida's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the

submission of false claims for payment by Florida in violation of the Florida False Claims Act, FL. STAT. § 68.081-68.090.

253. In addition, BMS/Sanofi fraudulently induced Florida's state review board to place Plavix on Florida's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Florida to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the Florida False Claims Act, FL. STAT. § 68.081-68.090.

254. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

255. By reason of the Defendants' unlawful acts, the State of Florida has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

256. The State of Florida is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

H. Eighth Cause of Action: Georgia State Law Claims for Violations of the Georgia False Medicaid Claims Act (GA. CODE 49-4-168 *et seq.*)

257. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

258. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Georgia under the Georgia State False Medicaid Claims Act, GA. CODE 49-4-168 et seq.

259. If the State of Georgia had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

260. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Georgia government while illegally and deceptively promoting Plavix to further increase Plavix sales within the State of Georgia.

261. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

262. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Georgia to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Georgia. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Georgia when Plavix did not in fact meet requirements for Georgia's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Georgia in violation of the Georgia State False Medicaid Claims Act, GA. CODE 49-4-168 et seq.

263. In addition, BMS/Sanofi fraudulently induced Georgia's state review board to place Plavix on Georgia's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Georgia to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the Georgia State False Medicaid Claims Act, GA. CODE 49-4-168 et seq.

264. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

265. By reason of the Defendants' unlawful acts, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

266. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

I. Ninth Cause of Action: Illinois State Law Claims for Violations of the Illinois Whistleblower Reward and Protection Act (740 ILCS 175, *et seq.*)

267. Dickson re-alleges and incorporates by reference each of the preceding paragraphs as if set forth fully herein.

268. Pursuant to Section 3 of the Illinois Whistleblower Reward and Protection Act, a person is liable to the state of Illinois for civil penalties and triple damages for any damage the state sustains as a result of fraud perpetrated by that person on the state, such as for knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval, or making or using false records

or statements to conceal, avoid or decrease an obligation to pay or transmit money or property to the state.

269. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Illinois government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Illinois and specifically within the Southern District of Illinois.

270. Over 40% of nationwide Plavix sales are covered by Government Payors. Illinois is the fifth most populous state in the United States. A significant percentage of Illinois Plavix sales are covered by Government Payors in Illinois.

271. BMS/Sanofi fraudulently induced Illinois's state review board to place Plavix on Illinois's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Illinois to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175, *et seq*.

272. If the State of Illinois had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the Plavix prescription.

273. Dickson brings this action for violations of the Illinois Whistleblower Reward and Protection Act.

J. Tenth Cause of Action: Indiana State Law Claims for Violations of the Indiana State False Claims and Whistleblowers Protection Act (IND. CODE ANN. § 5-11-5.5-1 – 5-11-5.5-18)

274. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

275. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Indiana under the Indiana State False Claims and Whistleblowers Protection Act, IND. CODE ANN. § 5-11-5.5-1 – 5-11-5.5-18.

276. If the State of Indiana had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the Plavix prescription.

277. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Indiana government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Indiana.

278. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

279. BMS/Sanofi fraudulently induced Indiana's state review board to place Plavix on Indiana's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Indiana to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the Indiana State False Claims and Whistleblowers Protection Act, IND. CODE ANN. § 5-11-5.5-1 – 5-11-5.5-18.

280. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

281. By reason of the Defendants' unlawful acts, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

K. Eleventh Cause of Action: Massachusetts State Law Claims for Violations of the Massachusetts False Claims Act (MASS. GEN. LAWS c.12 § 5(A))

282. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

283. This is a claim for treble damages and penalties against the Defendants on behalf of the Commonwealth of Massachusetts under the Massachusetts False Claims Act, MASS. GEN. LAWS c.12 § 5(A).

284. If the Commonwealth of Massachusetts had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

285. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Massachusetts government while illegally and deceptively promoting Plavix to further increase Plavix sales within the Commonwealth of Massachusetts.

286. By virtue of the above-described acts, Defendants knowingly made, used, or caused the Commonwealth of Massachusetts to approve and pay such false and fraudulent claims.

287. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Massachusetts to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Massachusetts. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Massachusetts when Plavix did not in fact meet requirements for Massachusetts's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Massachusetts in violation of the Massachusetts False Claims Act, MASS. GEN. LAWS c.12 § 5(A).

288. In addition, BMS/Sanofi fraudulently induced Massachusetts's state review board to place Plavix on Massachusetts's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Massachusetts to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false

claims in violation of the Massachusetts False Claims Act, MASS. GEN. LAWS c.12 § 5(A).

289. The Commonwealth of Massachusetts, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

290. By reason of the Defendants' unlawful acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

L. Twelfth Cause of Action: Michigan State Law Claims for Violations of the Michigan Medicaid False Claims Act (Mich. Comp. Laws §§ 400.601-400.613)

291. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

292. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Michigan under the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601-400.613.

293. If the State of Michigan had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

294. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Michigan government while illegally and deceptively promoting Plavix to further increase Plavix sales within the State of Michigan.

295. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

296. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Michigan to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Michigan. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Michigan when Plavix did not in fact meet requirements for Michigan's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Michigan in violation of the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601-400.613.

297. In addition, BMS/Sanofi fraudulently induced Michigan's state review board to place Plavix on Michigan's formulary for indications for which Plavix has

no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Michigan to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601-400.613.

298. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

299. By reason of the Defendants' unlawful acts, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

M. Thirteenth Cause of Action: Minnesota State Law Claims for Violations of the Minnesota False Claims Act (MINN. STAT. § 15.C01 *et. seq*)

300. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

301. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Minnesota under the Minnesota False Claims Act, MINN. STAT. § 15.C01 et. seq.

302. If the State of Minnesota had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

303. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Minnesota government while illegally and deceptively promoting Plavix to further increase Plavix sales within the State of Minnesota.

304. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Minnesota to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Minnesota. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Minnesota when Plavix did not in fact meet requirements for Minnesota's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by

Minnesota in violation of the Minnesota False Claims Act, MINN. STAT. § 15.C01 et. seq.

305. In addition, BMS/Sanofi fraudulently induced Minnesota's state review board to place Plavix on Minnesota's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Minnesota to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the Minnesota False Claims Act, MINN. STAT. § 15.C01 et. seq.

306. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of Minnesota to approve and pay such false and fraudulent claims.

307. By reason of the Defendants' unlawful acts, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

N. Fourteenth Cause of Action: Montana State Law Claims for Violations of the Montana False Claims Act (MONT. CODE ANN. §§ 17-8-401 – 17-8-412)

308. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

309. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Montana under the Montana False Claims Act, MONT. CODE ANN. §§ 17-8-401 – 17-8-412.

310. If the State of Montana had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

311. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Montana government while illegally and deceptively promoting Plavix to further increase Plavix sales within the State of Montana.

312. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

313. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Montana to impliedly make false certifications about Plavix's cost effectiveness

(and medical necessity) for the patient's treatment. For example, the Montana Medicaid program requires that prescribed drugs be "the most efficient and cost-effective," which Plavix was not. A prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Montana. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Montana when Plavix did not in fact meet requirements for Montana's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Montana in violation of the Montana False Claims Act, MONT. CODE ANN. §§ 17-8-401 – 17-8-412.

314. In addition, BMS/Sanofi fraudulently induced Montana's state review board to place Plavix on Montana's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Montana to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the Montana False Claims Act, MONT. CODE ANN. §§ 17-8-401 – 17-8-412.

315. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

316. By reason of the Defendants' unlawful acts, the State of Montana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

O. Fifteenth Cause of Action: Nevada State Law Claims for Violations of the Nevada False Claims Act (NEV. REV. STAT. ANN. §§ 357.01-.250)

317. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

318. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Nevada under the Nevada False Claims Act, NEV. REV. STAT. ANN. §§ 357.01-.250.

319. If the State of Nevada had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

320. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Nevada government while illegally and deceptively promoting Plavix to further increase Plavix sales within the State of Nevada.

321. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

322. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Nevada to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Nevada. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Nevada when Plavix did not in fact meet requirements for Nevada's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Nevada in violation of the Nevada False Claims Act, NEV. REV. STAT. ANN. §§ 357.01-.250.

323. In addition, BMS/Sanofi fraudulently induced Nevada's state review board to place Plavix on Nevada's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Nevada to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was

prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the Nevada False Claims Act, NEV. REV. STAT. ANN. §§ 357.01-.250.

324. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

325. By reason of the Defendants' unlawful acts, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

326. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

P. Sixteenth Cause of Action: New Jersey State Law Claims for Violations of the New Jersey False Claims Act (N.J. STAT. § 2A:32C-1-17)

327. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

328. This is a claim for treble damages and penalties against the Defendants on behalf of the State of New Jersey under the New Jersey False Claims Act, N.J. STAT. §2A:32C-1-17.

329. If the State of New Jersey had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

330. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the New Jersey government while illegally and deceptively promoting Plavix to further increase Plavix sales within the State of New Jersey.

331. By virtue of the above-described acts, Defendants knowingly made, used, or caused the State of New Jersey to approve and pay such false and fraudulent claims.

332. BMS/Sanofi's actions knowingly caused physicians and pharmacists in New Jersey to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in New Jersey. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in New Jersey when Plavix did not in fact meet requirements for New Jersey's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by New Jersey in violation of the New Jersey False Claims Act, N.J. STAT. §2A:32C-1-17.

333. In addition, BMS/Sanofi fraudulently induced New Jersey's state review board to place Plavix on New Jersey's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused New Jersey to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the New Jersey False Claims Act, N.J. STAT. §2A:32C-1-17.

334. The State of New Jersey, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

335. By reason of the Defendants' unlawful acts, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

Q. Seventeenth Cause of Action: New Mexico State Law Claims for Violations of the New Mexico Medicaid False Claims Act (N.M. STAT. ANN. § 27-14-1- - 27-14-15)

336. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

337. This is a claim for treble damages and penalties against all Defendants on behalf of the State of New Mexico under the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-1- 27-14-15.

338. If the State of New Mexico had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

339. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the New Mexico government while illegally and deceptively promoting Plavix to further increase Plavix sales within the State of New Mexico.

340. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

341. BMS/Sanofi's actions knowingly caused physicians and pharmacists in New Mexico to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in New Mexico. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in New Mexico

when Plavix did not in fact meet requirements for New Mexico's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by New Mexico in violation of the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-1- - 27-14-15.

342. In addition, BMS/Sanofi fraudulently induced New Mexico's state review board to place Plavix on New Mexico's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused New Mexico to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-1- - 27-14-15.

343. The State of New Mexico, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

344. By reason of the Defendants' unlawful acts, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

R. Eighteenth Cause of Action: New York State Law Claims for Violations of the New York False Claims Act (N.Y. St. Finance Law § 187 *et seq*.)

345. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

346. This is a claim for treble damages and penalties against all Defendants on behalf of the State of New York under the New York False Claims Act, N.Y. St. Finance Law §187 et seq.

347. If the State of New York had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the Plavix prescription.

348. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the New York government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of New York.

349. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted

material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

350. BMS/Sanofi fraudulently induced New York's state review board to place Plavix on New York's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused New York to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the New York False Claims Act, N.Y. St. Finance Law §187 et seq.

351. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

352. By reason of the Defendants' unlawful acts, the State of New York has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

353. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

S. Nineteenth Cause of Action: North Carolina State Law Claims for Violations of the North Carolina False Claims Act (N.C. GEN. STAT. § 1-605 – 618, § 108A-63)

354. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

355. This is a claim for treble damages and penalties against the Defendants on behalf of the State of North Carolina under the North Carolina False Claims Act, N.C. GEN. STAT. § 1-605-618, § 108A-63.

356. If the State of North Carolina had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

357. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the North Carolina government while illegally and deceptively promoting Plavix to further increase Plavix sales within the State of North Carolina.

358. BMS/Sanofi's actions knowingly caused physicians and pharmacists in North Carolina to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a

prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in North Carolina. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in North Carolina when Plavix did not in fact meet requirements for North Carolina's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by North Carolina in violation of the North Carolina False Claims Act, N.C. GEN. STAT. § 1-605-618, § 108A-63.

359. In addition, BMS/Sanofi fraudulently induced North Carolina's state review board to place Plavix on North Carolina's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused North Carolina to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the North Carolina False Claims Act, N.C. GEN. STAT. § 1-605-618, § 108A-63.

360. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of North Carolina to approve and pay such false and fraudulent claims.

361. By reason of the Defendants' unlawful acts, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

T. Twentieth Cause of Action: Oklahoma State Law Claims for Violations of the Oklahoma False Claims Act (63 OKLA. STAT. §§ 5053-5053.7)

362. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

363. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Oklahoma under the Oklahoma False Claims Act, 63 OKLA. STAT. §§ 5053-5053.7.

364. Relator incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

365. If the State of Oklahoma had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

366. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Oklahoma government while illegally and

deceptively promoting Plavix to further increase Plavix sales within the State of Oklahoma.

367. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Oklahoma to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Oklahoma. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Oklahoma when Plavix did not in fact meet requirements for Oklahoma's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Oklahoma in violation of the Oklahoma False Claims Act, 63 OKLA. STAT. §§ 5053-5053.7.

368. In addition, BMS/Sanofi fraudulently induced Oklahoma's state review board to place Plavix on Oklahoma's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Oklahoma to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions

before the formulary committee caused the payment of false claims in violation of the Oklahoma False Claims Act, 63 OKLA. STAT. §§ 5053-5053.7.

369. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of Oklahoma to approve and pay such false and fraudulent claims.

370. By reason of the Defendants' unlawful acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

U. Twenty-First Cause of Action: Rhode Island State Law Claims for Violations of Rhode Island's State False Claims Act (R.I. GEN. LAWS §§ 9-1.1-1 – 9-1.1-8)

371. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

372. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Rhode Island's False Claims Act, R.I. GEN. LAWS § 9-1.1-3.

373. If the State of Rhode Island had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

374. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Rhode Island government while illegally and

deceptively promoting Plavix to further increase Plavix sales within the State of Rhode Island.

375. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Rhode Island to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Rhode Island. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Rhode Island when Plavix did not in fact meet requirements for Rhode Island's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Rhode Island in violation of the Rhode Island's False Claims Act, R.I. GEN. LAWS § 9-1.1-3.

376. In addition, BMS/Sanofi fraudulently induced Rhode Island's state review board to place Plavix on Rhode Island's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Rhode Island to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions

before the formulary committee caused the payment of false claims in violation of the Rhode Island False Claims Act, R.I. GEN. LAWS § 9-1.1-3.

377. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of Rhode Island to approve and pay such false and fraudulent claims.

378. By reason of the Defendants' unlawful acts, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

V. Twenty-Second Cause of Action: Tennessee State Law Claims for Violations of the Tennessee Medicaid False Claims Act (TENN. CODE. ANN. §§ 71-5-181 to -185)

379. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

380. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Tennessee under the Tennessee Medicaid False Claims Act, TENN. CODE. ANN. §§ 71-5-181 to -185.

381. If the State of Tennessee had known of the false statements disseminated by BMS/Sanofi in support of Plavix, it would have refused to authorize payment for certain Plavix prescriptions.

382. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Tennessee government while illegally and

deceptively promoting Plavix to further increase Plavix sales within the State of Tennessee.

383. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

384. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Tennessee to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Tennessee. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Tennessee when Plavix did not in fact meet requirements for Tennessee's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Tennessee in violation of the Tennessee Medicaid False Claims Act, TENN. CODE. ANN. §§ 71-5-181 to -185.

385. In addition, BMS/Sanofi fraudulently induced Tennessee's state review board to place Plavix on Tennessee's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive.

Thus, BMS/Sanofi knowingly caused Tennessee to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the Tennessee Medicaid False Claims Act, TENN. CODE. ANN. §§ 71-5-181 to -185.

386. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

387. By reason of the Defendants' unlawful acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

388. The State of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

W. Twenty-Third Cause of Action: Texas State Law Claims for Violations of the Texas Medicaid Fraud Prevention Act (TEX. HUM. RES. CODE ANN 36.001-.132)

389. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

390. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Texas under the Texas Medicaid Fraud Prevention Act, TEX. HUM. RES. CODE ANN. 36.001–.132.

391. If the State of Texas had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the Plavix prescription.

392. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Texas government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Texas.

393. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

394. BMS/Sanofi fraudulently induced Texas's state review board to place Plavix on Texas's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Texas to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain

formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of the Texas Medicaid Fraud Prevention Act, TEX. HUM. RES. CODE ANN. 36.001–.132.

395. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

396. By reason of the Defendants' unlawful acts, the State of Texas has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

397. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

X. Twenty-Fourth Cause of Action: Virginia State Law Claims for Violations of the Virginia Fraud Against Taxpayers Act (VA CODE ANN. 8.01-2.16. 1-216.19)

398. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

399. This is a claim for treble damages and penalties against the Defendants on behalf of the Commonwealth of Virginia under the Virginia Fraud Against Taxpayers Act, Vested. Ch. 842, Article 19.1, § 8.01-216.1 et seq.

400. If the Commonwealth of Virginia had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the Plavix prescription.

401. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Virginia government while illegally and deceptively promoting Plavix to further increase Plavix sales within the Commonwealth of Virginia.

402. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

403. BMS/Sanofi fraudulently induced Virginia's state review board to place Plavix on Virginia's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Virginia to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of

the Virginia Fraud Against Taxpayers Act, Vested. Ch. 842, Article 19.1, § 8.01-216.1 et seq.

404. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

405. By reason of the Defendants' unlawful acts, the State of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

406. The State of Virginia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Y. Twenty-Fifth Cause of Action: Wisconsin State Law Claims for Violations of the Wisconsin False Claims Act (WIS. STAT. § 20.931)

407. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

408. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Wisconsin's False Claims Act, WIS. STAT. § 20.931.

409. If the State of Wisconsin had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the Plavix prescription.

410. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Wisconsin government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Wisconsin.

411. BMS/Sanofi's actions knowingly caused physicians and pharmacists in Wisconsin to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity) for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in Wisconsin. BMS/Sanofi's misrepresentations, however, caused physicians to prescribe Plavix in Wisconsin when Plavix did not in fact meet requirements for Wisconsin's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Wisconsin in violation of the State of Wisconsin's False Claims Act, WIS. STAT. § 20.931.

412. In addition, BMS/Sanofi fraudulently induced Wisconsin's state review board to place Plavix on Wisconsin's formulary for indications for which

Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused Wisconsin to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of State of Wisconsin's False Claims Act, WIS. STAT. § 20.931.

413. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of Wisconsin to approve and pay such false and fraudulent claims.

Z. Twenty-Sixth Cause of Action: District of Columbia Claims for Violations of the District of Columbia Procurement Reform Amendment Act (D.C. CODE ANN. §§ 2-308.13-.15)

414. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

415. This is a claim for treble damages and penalties against BMS/Sanofi on behalf of the District of Columbia under the District of Columbia Procurement Reform Amendment Act.

416. If the District of Columbia had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the Plavix prescription.

417. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the District of Columbia government while illegally and deceptively promoting Plavix to further increase Plavix sales within the District of Columbia.

418. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

419. BMS/Sanofi fraudulently induced the District of Columbia's state review board to place Plavix on the District of Columbia's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused the District of Columbia to become obligated to pay for Plavix when Plavix was prescribed for these indications even though—for these indications—Plavix did not meet formulary requirements. Thus, when Plavix was prescribed for certain formulary indications, BMS/Sanofi's fraudulent actions before the formulary committee caused the payment of false claims in violation of State of the District of Columbia Procurement Reform Amendment Act, D.C. CODE ANN. §§ 2-308.13-.15.

420. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or

presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

421. By reason of the Defendants' unlawful acts, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

422. The District of Columbia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

VII.
DEMAND FOR JURY TRIAL

423. Pursuant to Federal Rule of Civil Procedure 38, Dickson demands a trial by jury.

VIII.
PRAYER

WHEREFORE, Relator Elisa Dickson respectfully requests that this Court enter judgment on behalf of the United States against Defendants for the following:

a. Damages in the amount of three (3) times the actual damages suffered by the United States as a result of Defendants' conduct;

b. Civil penalties against Defendants up to $10,000, plus the appropriate amount of inflation, for each violation of 31 U.S.C. § 3729;

c. Dickson be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

d. Dickson be awarded all costs and expenses of this litigation, including attorneys' fees and costs of court; and

e. All other relief on behalf of the United States Government to which it may be entitled and that the Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of California against Defendants for the following:

a. That by reason of the aforementioned violations of the California False Claims Act that this Court enter judgment in the State of California's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that California has sustained because of Defendants' actions, plus a civil penalty of not more than $10,000 for each violation of CAL. GOV. CODE §12651(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to CAL. GOV. CODE §12652(g)(2) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of California and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Colorado against Defendants for the following:

a. That by reason of the aforementioned violations of the Colorado false claims provisions that this Court enter judgment in the State of Colorado's favor and against Defendants in an amount equal to not less than three times the amount of damages that Colorado has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of the Colorado Medicaid False Claims Act C.R.S. § 25.5-4-304 et seq.;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to C.R.S. § 25.5-4-306(4) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Colorado and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Connecticut against Defendants for the following:

a. That by reason of the aforementioned violations of the Connecticut false claims provisions that this Court enter judgment in the State of Connecticut's favor and against Defendants in an amount equal to not less than three times the amount of damages that Connecticut has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of the Connecticut False Claims Act, CONN. GEN. STAT. ANN. § 17b-301a et seq.;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to CONN. GEN. STAT. ANN. § 17b-301f and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Connecticut and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Delaware against Defendants for the following:

a. That by reason of the aforementioned violations of the Delaware false claims provisions that this Court enter judgment in the State of Delaware's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of

damages that Delaware has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 6 DEL. CODE ANN. § 1201(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to 6 DEL. CODE ANN. § 1205(a) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Delaware and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Florida against Defendants for the following:

a. That by reason of the aforementioned violations of the Florida false claims provisions that this Court enter judgment in the State of Florida's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Florida has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of FLA. STAT. ANN. § 68.082(2)(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant FLA. STAT. ANN. § 68.085(1)-(2) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Florida and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Georgia against Defendants for the following:

a. That by reason of the aforementioned violations of the Georgia False Medicaid Claims Act that this Court enter judgment in the State of Georgia's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the Georgia has sustained because of Defendants' actions, plus a civil penalty of not more than $10,000 for each violation of the GA. CODE ANN. § 49-4-168.1;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the GA. CODE ANN. § 49-4-168.2 (I) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Georgia and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Illinois against Defendants for the following:

a. Damages in the amount of three (3) times the actual damages suffered by the State of Illinois as a result of Defendants' conduct pursuant to 740 ILCS 175;

b. Civil penalties against Defendants up to $11,000 for each violation of 740 ILCS 175;

c. Relator be awarded the maximum amount allowed pursuant to 740 ILCS 175/4(d);

d. Repayment of any excess benefits or payments received pursuant to 305 ILCS 5/8A-7;

e. Civil penalties against Defendants consisting of the interest on the amount of excess benefits or payments pursuant to 305 ILCS 5/8A-7;

f. Damages in the amount of three (3) times the amount of such excess benefits or payments pursuant to 305 ILCS 5/8A-7;

g. Damages in the amount of $2,000 for each excessive claim for benefits or payments pursuant to 305 ILCS 5/8A-7;

h. Relator be awarded all costs and expenses of this litigation, including attorneys' fees and costs of court; and

i. All other relief on behalf of the State of Illinois to which it may be entitled and that the Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Indiana against Defendants for the following:

a. That by reason of the aforementioned violations of the Indiana State False Claims and Whistleblowers Protection Act that this Court enter judgment in the State of Indiana's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the Indiana has sustained because of Defendants' actions, plus a civil penalty of less than $5,000 for each violation of the IND. CODE ANN. § 5-11-5.5-2;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the IND. CODE ANN. § 5-11-5.5-6 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Indiana and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the Commonwealth of Massachusetts against Defendants for the following:

a. That by reason of the aforementioned violations of the Massachusetts False Claims Act provisions that this Court enter judgment in the Commonwealth of Massachusetts's favor and against Defendants in an amount three times the amount of damages that Massachusetts has

sustained because of Defendants' actions for violation of the Massachusetts False Claims Act, MASS. GEN. LAWS c.12 § 5(A);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Massachusetts False Claims Act, MASS. GEN. LAWS c.12 § 5(A) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the Commonwealth of Massachusetts and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Michigan against Defendants for the following:

a. That by reason of the aforementioned violations of the Michigan State Medicaid False Claims Act that this Court enter judgment in the State of Michigan's favor and against Defendants in an amount equal to three times the amount of damages that the Michigan has sustained because of Defendants' actions, plus a civil penalty of equal to the full amount Defendants unjustly received as a result of its unlawful conduct for violating MICH. COMP. LAWS§ 400.603, 606 and 607;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the MICH. COMP. LAWS § 400.610 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Michigan and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Minnesota against Defendants for the following:

a. That by reason of the aforementioned violations of the Minnesota False Claims provisions that this Court enter judgment in the State of Minnesota's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of Minnesota has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of MINN. STAT. § 15.C01 *et. seq*;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant MINN. STAT. § 15.C01 *et. seq* and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Minnesota and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Montana against Defendants for the following:

a. That by reason of the aforementioned violations of the Montana False Claims Act that this Court enter judgment in the State of Montana's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the Montana has sustained because of Defendants' actions, plus a civil penalty of not more than $10,000 for each violation of the MONT. CODE ANN. § 17-8-403;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the MONT. CODE ANN. § 17-8-410 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Montana and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Nevada against Defendants for the following:

a. That by reason of the aforementioned violations of the Nevada false claims provisions that this Court enter judgment in the State of Nevada's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Nevada has sustained because of Defendants' actions, plus a civil penalty of not more than $10,000 for each violation of the NEV. REV. STAT. ANN. § 357.014(1)(c);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant NEV. REV. STAT. ANN. § 357.210(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Nevada and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of New Jersey against Defendants for the following:

a. That by reason of the aforementioned violations of the New Jersey False Claims provisions that this Court enter judgment in the State of New Jersey's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of New Jersey has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of N.J. STAT. § 2A:32C-1-17;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.J. STAT. § 2A:32C-1-17 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of New Jersey and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of New Mexico against Defendants for the following:

a. That by reason of the aforementioned violations of the New Mexico False Claims Act provisions that this Court enter judgment in the State of Mexico's favor and against Defendants in an amount three times the amount of damages that New Mexico has sustained because of Defendants' actions for violation of the N.M. STAT. ANN. § 27-14-4;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.M. STAT. ANN. § 27-14-9 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of New Mexico and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of New York against Defendants for the following:

a. That by reason of the aforementioned violations of the New York False Claims Act provisions that this Court enter judgment in the State of New York's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that New York has sustained because of Defendants' actions,

plus a civil penalty of not less than $6,000 and not more than $12,000 for each violation of N.Y. STATE FIN. L. § 189;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.Y. STATE FIN. L. § 119(6) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of New York and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of North Carolina against Defendants for the following:

a. That by reason of the aforementioned violations of the North Carolina False Claims provisions that this Court enter judgment in the State of North Carolina's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of North Carolina has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of N.C. GEN. STAT. § 1-605-618, §108A-63;

b. That Relator, as Qui Tam Plaintiff, be awarded the maximum amount allowed pursuant the N.C. GEN. STAT. § 1-605-618, §108A-63 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of North Carolina and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Oklahoma against Defendants for the following:

a. That by reason of the aforementioned violations of Oklahoma's False Claims provisions that this Court enter judgment in the State of Oklahoma's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of 63 OKLA. STAT. § 5053.1.4;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant 63 OKLA. STAT. § 5053.1.4 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Oklahoma and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Rhode Island against Defendants for the following:

a. That by reason of the aforementioned violations of the Rhode Island's false claims provisions that this Court enter judgment in the State of Rhode Island's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Rhode Island has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of Rhode Island's False Claims Act (R.I. GEN. LAWS § 9-1.1-3);

b. That Relator, as Qui *Tam* Plaintiff, be awarded the maximum amount allowed pursuant to R.I. GEN. LAWS § 9-1.1-3 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Rhode Island and Relator each have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Tennessee against Defendants for the following:

a. That by reason of the aforementioned violations of the Tennessee false claims provisions that this Court enter judgment in the State of Tennessee's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Tennessee has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of the TENN. CODE ANN. § 71-5-182(a)(1)(C);

b. That Relator, as Qui *Tam* Plaintiff, be awarded the maximum amount allowed pursuant TENN. CODE ANN. § 71-5-183(c)(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Tennessee and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Texas against Defendants for the following:

a. That by reason of the aforementioned violations of the Texas Medicaid Fraud Prevention Statute that this Court enter judgment in the State of Texas's favor and against Defendants in an amount equal to two times the amount of damages that the state of Texas has

sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $15,000 for each violation of TEX. HUM. RES. CODE ANN. § 36.002(8) that results in injury to an elderly person, a disabled person, or a person younger than 18 years of age, or not less than $1,000 and not more than $10,000 for each violation of the TEX. HUM. RES. CODE ANN. § 36.002(8) that does not result in an injury to a person;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant TEX. HUM. RES. CODE ANN. § 36.110 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Texas and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the Commonwealth of Virginia against Defendants for the following:

a. That by reason of the aforementioned violations of the Virginia Fraud Against Taxpayers Act that this Court enter judgment in the Commonwealth of Virginia's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the Commonwealth of Virginia has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of the VA. CODE ANN. § 8.01-216.3(A)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant VA. CODE ANN. § 8.01-216.7 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the Commonwealth of Virginia and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Wisconsin against Defendants for the following:

a. That by reason of the aforementioned violations of Wisconsin's False Claims provisions that this Court enter judgment in the State of Wisconsin's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of Wis. Stat. § 20.931;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Wis. Stat. § 20.931 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the State of Wisconsin and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the District of Columbia against Defendants for the following:

a. That by reason of the aforementioned violations of the District of Columbia false claims provisions that this Court enter judgment in the District of Columbia's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of DC. CODE ANN. §2-308.14(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant DC. CODE ANN. §2-308.15(f)(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That the District of Columbia and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests any such other and further relief to which she may be justly entitled.

DATED: August 16, 2016.

Respectfully submitted,

BY: *s./ Christopher Cueto*

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